Exhibit A

NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

New Case Electronically Filed: COMPLAINT
May 17, 2022 14:05

By: WILLIAM A. CARLIN 0009144

Confirmation Nbr. 2552529

VESELJKO STOJANOVIC, ET AL

vs.

BOSTON SCIENTIFIC CORPORATION, ET AL

CV 22 963537

Judge: ANDREW J. SANTOLI

Pages Filed: 22

IN COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC 3013 Arrow Lane Parma, Ohio 44134 And RANKA STOJANOVIC 3013 Arrow Lane Parma, Ohio 44134 Plaintiffs vs. BOSTON SCIENTIFIC CORPORATION c/o Its Statutory Agent Corporation Service Company 84 State Street Boston, MA 02109 And CLEVELAND CLINIC FOUNDATION AKA CLEVELAND CLINIC c/o Its Statutory Agent CT Corporation System 1300 East 9th Street Cleveland, OH 44114 And MOHAMED ELTEMAMY, M.D. Cleveland Clinic Foundation 9500 Euclid Ave. Cleveland, OH 44195	CASE NO: JUDGE **COMPLAINT** Affidavit of Merit included herein. *Jury Demand Endorsed herein*

Electronically Filed 05/17/2022 14:05 / / CV 22 963537 / Confirmation Nbr. 2552529 / CLAJB

And

JOHN/JANE DOE (1-5)
Any Physician or other Health Care Provider responsible for the Care and treatment of Veseljko Stojanovic (names and addresses unknown)

And

DOE CORPORATION/ PARTNERSHIP 1-5)
Any Corporation or other Business Entity whose Employees and/or Agents were responsible for the care and treatment of Veseljko Stojanovic, (names and addresses unknown)

And

JOHN/JANE ROES (5-10)
Any representative of Boston Scientific Corporation who delivered the Rezum product into Ohio (names and addresses unknown)

And

JOHN/JANE ROES (10-25)
Individuals or corporations who designed or delivered the Rezum product into Ohio (names and Addresses unknown)

Defendants

Now comes Plaintiffs, Veseljko and Ranka Stojanovic and for their cause of action against the Defendants state the following:

FACTS COMMON TO ALL COUNTS

1. At all times herein, Veseljko Stojanovic ("Mr. Stojanovic") and Ranka Stojanovic

("Mrs. Stojanovic") (collectively "Plaintiffs") were husband and wife and were residents of Cuyahoga County, Ohio.

2. The Defendant, Cleveland Clinic Foundation ("Cleveland Clinic") is and was a healthcare provider who held itself out to the public, including the Plaintiffs, as having the requisite skilled personnel, staff and equipment to render quality Healthcare Services and at all times pertinent herein, were responsible for its employees and apparent employees, including Dr. Mohamed Eltemamy ("Dr. Eltemamy") who rendered treatment and care to Mr. Stojanovic, while within the scope or apparent scope of his employment with Cleveland Clinic.

3. At all times relevant herein, Defendants John/Jane Doe (1-5) and Doe Corporation/Partnership (1-5) were physicians or other licensed health care providers responsible for the care and treatment of Plaintiff and who held themselves out to the general public, including Plaintiff, as being capable of providing quality medical care or were Ohio corporations or other business entities licensed to do business in Ohio, which employed and/or contracted with medical, nursing and other health care professionals responsible for the care and treatment of Plaintiff. It is further believed that Defendants John/Jane Doe (1-5) were employees and/or apparent employees of Cleveland Clinic. Despite the exercise of due diligence, the Plaintiff has been unable to ascertain the true identity of these Defendants.

4. At all times herein, Boston Scientific Corporation ("Boston Scientific") was a Corporation or other business entity with its principal place of business in Massachusetts and was engaged in doing business throughout the state of Ohio, and

elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise placed in the stream of commerce a certain medical device, including, but not limited to, a certain product known as Rezum, which is sold as a delivery system kit to treat benign prostatic hyperplasia ("BPH") together with its component parts, (hereinafter referred to as "Rezum"), which product was delivered and sold in the state of Ohio and elsewhere.

5. At all times material to the within cause of action, Defendants John/Jane Doe (5-10) Representatives of Boston Scientific were engaged in doing business throughout the State of Ohio and elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise placed in the stream of commerce the Rezum delivery system, in Ohio and elsewhere. Despite diligent efforts, the identity of John/Jane Doe Representative of Boston Scientific remains unknown.

6. At all times material to the within cause of action, Defendants Doe Corporation 1-5 and Defendants John/Jane Roes (10-25) were individuals and/or corporations or partnerships engaged in doing business throughout the State of Ohio, and elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise took action with respect to certain medical devices, including the Rezum delivery system, which was placed into interstate commerce, in Ohio and elsewhere.

7. On or about June 2, 2021, the Plaintiff underwent a cystoscopy utilizing Rezum, to treat BPH and as a result of Defendant's failure to provide the Plaintiff with

competent, safe and acceptable care and treatment, the Plaintiff was permanently injured.

8. The defendant, Dr. Eltemamy, negligently utilized the Rezum product and/or the Rezum product was defective, which caused permanent injury to Plaintiff's prostate and/or bladder and/or bladder neck and plaintiff is now unable to control his ability to urinate. Pursuant to R.C. § 2315.18 (B)(3)(a), the Plaintiff has lost the use of a bodily organ system and therefore there is no limitation on the amount of compensatory damages that represent damages for non-economic loss. (The Affidavit of Merit of Dr. David Chaikin is attached as Exhibit "A".)

9. As a direct and proximate cause of the negligence of Dr. Eltemamy in the utilization of the Rezum product and/or a defective Rezum product, Mr. Stojanovic was required to undergo further surgical procedures, including the placement of a suprapubic tube to drain urine from his bladder. As a proximate cause of the additional post Rezum surgical procedures, Mr. Stojanovic sustained a permanent physical deformity and pursuant to R.C. §2315.18 (B)(3)(a), there is no limitation on the amount of compensatory damages that represents damages for non-economic loss.

10. At all times relevant herein, the Defendant, Dr. Eltemamy, was and is an individual who was licensed to practice medicine in the state of Ohio and was employed by Cleveland Clinic and/or was operating within the scope of his employment or apparent employment with Cleveland Clinic.

11. At all times herein, Dr. Eltemamy was acting within the scope and course of his employment and/or apparent employment with Cleveland Clinic and held himself

out to the public, including the Plaintiff, as having the requisite skills and ability to render quality Healthcare Services.

12. The Defendants negligently provided services to the Plaintiff and they failed to follow, meet and conform to the standard of care in providing healthcare services under similar circumstances, in Cuyahoga County and other places.

13. The Defendants were negligent in failing to hire employees that could and would adopt and practice accepted procedures for providing healthcare to patients and the Defendants failed to enforce said procedures in accordance with accepted practices in providing healthcare in the counties of Northern Ohio and other similar communities in the United States.

14. The Defendants failed to hire employees who would follow procedures and they failed to establish appropriate training, standards and procedures for those employees providing services to their patients.

COUNT I
NEGLIGENCE

15. Plaintiffs hereby incorporate paragraphs 1 through 14 as though fully rewritten herein.

16. As a direct and proximate result of the negligence of all of the defendants herein, the Plaintiff was denied effective medical, nursing and related Healthcare Services that were administered on/or about June 2, 2021 and thereafter at the Cleveland Clinic which resulted in permanent injury to the Plaintiff.

COUNT II
RES IPSA LOQUITUR

17. Plaintiffs hereby incorporate paragraphs 1 through 16 as if fully rewritten herein.

18. The Plaintiffs further state that this is the kind of injury that does not normally occur in the absence of negligence. (Res Ipsa Loquitur.)

COUNT III

19. Plaintiffs hereby incorporate paragraphs 1 through 18 as if fully rewritten herein.

20. It is believed and therefore averred that prior to on/or about June 2, 2022, representatives of Boston Scientific, the names and identities remain unknown despite diligent efforts to determine who they were, made affirmations, promises and descriptions that the Rezum delivery system was safe and fit for its intended use.

21. It is believed and therefore averred, that Boston Scientific failed to require certifications of physicians utilizing the Rezum delivery system, to ensure that those physicians utilizing Rezum were properly trained on the product, including, but not limited to, a complete understanding of the application of treatments and potential consequences thereof.

22. It is believed and therefore averred, that Boston Scientific, direct or indirectly, failed to properly train and instruct Dr. Eltemamy in the proper and safe use of the Rezum delivery system, or to insure that users of the product were properly trained prior to Dr. Eltemamy utilizing the said system on or about June 2, 2022.

23. At all times relevant herein, the United States Food and Drug Administration ("F.D.A.") was and is the federal agency of the United States responsible for approving medical devices pursuant to the medical device Amendments of 1976 to the Food Device Cosmetic Act ("FDCA").

24. In effect, the F.D.A. enforces the FDCA and ensures among other things, that

medical devices intended for use in human beings are safe and effective for its intended use, and that the physicians responsible for utilizing the device, are properly trained and that the labeling of such medical devices are true and accurate information. The F.D.A. requires that all medical devices must be demonstrated to be safe and effective for each intended use. A manufacturer is required to give adequate directions for the use of a medical device such that a "Layman can use a device safely and for the purpose for which it is intended", 21 C. F. R. § 810.5 (2012) and to conform to Section 801.15 requirements governing the appearance of the label.

25. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling and false and misleading labeling is considered misbranded, which is prohibited. (21 U.S.C. § 321, 352 and 331).

26. The distribution of a misbranded medical device is prohibited pursuant to 21 U.S.C. § 331 (a), (k)(2012) and 21 U.S.C. § 352 (F) (2012).)

27. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written when the manufacturer has failed to disclose those adverse events to the F.D.A. or failed to determine the causes of the adverse events. Therefore, the labeling becomes inadequate, and the product is misbranded.

28. Pursuant to the FDCA and F.D.A.'s implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the products risks,

particularly those risks that have been gleaned from adverse events reported by physicians and consumers use of the Rezum product. Consequently, in order to comply with the F.D.A.'s implementing regulations, such promotional pieces must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product, as suggested in the promotional piece or from reported adverse events. A medical device, including the Rezum product, distributed by Boston Scientific, is deemed to be misbranded if its labeling is false or misleading in any particular regard. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about adverse events that can result from use of the product.

29. Boston Scientific is further required to report to the F.D.A., "no later than 30 calendar days after the day: the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer may have caused or contributed to death or serious injury or malfunctioned. (21 C.F.R. Section 803.50 (a) (2012).

30. Reports to the F.D.A. are to contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. (21 C.F.R. § 803.50 (a) (2012).

31. Manufacturers, like Boston Scientific, are required to make periodic reports to the

F.D.A. regarding approved devices, such reports must include summaries of unpublished reports of data from any clinical investigation or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to Boston Scientific. It is also required that any negative or harmful reports in the scientific literature concerning the device and known to or that reasonably should be known to Boston Scientific be divulged to users of the device. (21 C. F. R. § 814.84 (b)(2)(2012)). Further, Boston Scientific had a continuing duty to monitor the Rezum product after premarket approval and to discover and report to the F.D.A. any complaints about the product's performance and any adverse events of which it became aware and that are or may be attributable to the Rezum delivery system or potential misuse of the system by physicians.

32. Boston Scientific is further required to establish internal procedures for reviewing complaints and adverse event reports. Consequently, Boston Scientific is required to "establish and maintain" an adverse event database in which they describe in every individual any adverse event report, whether remedial action was taken with regard to the adverse event and whether the remedial action was reported to the F.D.A as a removal or correction of the device. (21 C.F.R. § 803.50 (2012)).

33. Boston Scientific is further required to disclose any reportable medical device reporting event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, within 5 days after becoming aware of such event or events.

34. It is believed, and therefore averred, that Boston Scientific violated the aforementioned statutes and regulations by falsely and misleadingly promoting the

Rezum delivery system, by failing to report to the F.D.A. adverse events, by failing to timely conduct failure investigations and analysis, by failing to timely report any and all information concerning product failures and corrections, by failing to inform the F.D.A. of unanticipated adverse events, by failing to report increases in the incidence of adverse events and device failures necessitating a labeling, manufacturing or device notification or warning, failed to conduct necessary design validation's, selling and distributing a misbranded product by failing to disclose the potential risks of the Rezum delivery system, including the consequences of overtreating.

35. It is believed and therefore averred that an unknown representative of Boston Scientific was present when Dr. Eltemamy utilized the Rezum delivery system in the course of the procedure that was administered to the Plaintiff at the Cleveland Clinic on or about June 2, 2021 and negligently misguided Dr. Eltemamy in the use of the Rezum product or negligently failed to intervene when it would have been appropriate to do so.

36. The Manufacturer and User Facility Device Experience ("MAUDE") represents reports of adverse events involving medical devices, including the Rezum delivery system manufactured by Boston Scientific. It is believed and therefore averred that the utilization of Rezum resulted in over 300 adverse events by patients treated with the Rezum delivery system and failed to warn the Plaintiff's healthcare providers and/or the Plaintiff of those risks of the procedure, wherein the Rezum delivery system is utilized. (The MAUDE adverse events for Rezum cannot be attached, will be made available to the Court and any Defendant and are

incorporated herein by reference.)

37. As a direct and proximate result of the actions and/or inactions of the Defendants Boston Scientific, the Plaintiff sustained permanent injury which is requiring the Plaintiff to undergo additional procedures and surgeries to correct the injuries that he sustained as a result of the Rezum procedure.

COUNT IV
NEGLIGENCE PER SE

38. Plaintiffs hereby incorporate paragraphs 1 through 37 as if fully rewritten herein.

39. Defendant Boston Scientific had an obligation to follow those laws and regulations set forth by the F.D.A., regarding the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, product preparation for use, and warning of the risks and dangers of the Rezum delivery system.

40. Boston Scientific failed to comply with the legal requirements set forth by the F.D.A., in that it failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures, corrections, malfunctions, and injuries; failed to timely and fully inform F.D.A., physicians and patients of unanticipated adverse effects, increases in the incidence of adverse effects, for failures of the Rezum delivery system necessitating a labeling, manufacturing or device modification, they failed to conduct necessary design validations; and sold misbranded and mislabeled Rezum devices and failed to warn doctors and patients of the adverse events, injuries and malfunctions of the Rezum delivery system, all of which constitutes negligence per se and which caused injury to the Plaintiff.

COUNT V
BREACH OF EXPRESS WARRANTY

41. Plaintiffs hereby incorporate paragraphs 1 through 40 as if fully rewritten herein.

42. As a direct and proximate result of the actions and/or inactions of Defendant, Boston Scientific Corporation and/or its unknown affiliates and/or agents set forth in the Fictitious Names paragraphs of this Complaint, there was a breach of express warranty regarding the Rezum delivery device that was placed into the stream of commerce by Boston Scientific, which caused Plaintiff to sustain serious and permanent personal injuries requiring the care and treatment of physicians and medication and has been and will in the future, continue to be hampered in his daily routines.

43. The Defendant's representations and promises regarding the Rezum delivery system, had the natural tendency to and did, and to those who are in need of BPH treatment, including plaintiff herein, to utilize Rezum in reliance upon those representations.

44. The Rezum delivery system, did not conform to Boston Scientific's representations that the device was safe and would not produce serious side effects. The Rezum delivery system, did not conform to Boston Scientific's promises, descriptions and were not adequately packaged, labeled, promoted, or fit for the ordinary purpose for which it was intended. The defendants breached their express warranties to plaintiffs, including a warranty that those physicians and surgeons utilizing the Rezum delivery system would be properly trained in all aspects of its use, and properly certified in using Rezum. The defendants breached their express

warranties to plaintiffs in violation of applicable statutes and common-law.

45. Through Boston Scientific's public statements, descriptions of the device, and promises relating to the Rezum delivery system, Defendant's expressly warranted that the device was efficacious and safe for its intended use. Plaintiffs further allege that all written materials that the Defendant utilized, including on the websites, led the plaintiff to reasonably believe that the Rezum delivery system, would be safe, and if there were adverse events of potential risks of using the device, that Boston Scientific would provide warnings regarding those adverse events and risks.

COUNT VI
BREACH OF IMPLIED WARRANTIES

46. Plaintiffs hereby incorporate paragraphs 1 through 45 as if fully rewritten herein.

47. The Defendant, Boston Scientific, placed the Rezum product into the stream of commerce and intended that the Rezum delivery system be used in the manner that the Plaintiff and his physician herein used it. When the Rezum system was used in the intended manner, the Defendants impliedly warranted each device to be safe and fit for such use; and warranted that each of the devices was adequately tested and those physicians utilizing Rezum were properly trained and warned of potential injuries and malfunctions that users of the Rezum delivery system sustained as set forth in MAUDE.

48. The Defendants breach of the implied warranties caused injury to the Plaintiffs.

COUNT VII
BREACH OF WARRANTY AS TO MERCHANTABILITY

49. Plaintiffs hereby incorporate paragraphs 1 through 48 as if fully rewritten herein.

50. At all times herein, Boston Scientific was a merchant with respect to the Rezum

delivery system.

51. The Rezum delivery system was defectively designed and/or manufactured and was distributed and sold without the provision of reasonable instructions, training or warnings regarding the foreseeable risk of harm posed by the device to patients, including the Plaintiff.

52. The Plaintiff was a foreseeable user and was in privity with the Defendants.

53. The Rezum delivery system reached the Plaintiff without substantial changes in the condition in which the device was manufactured and sold by the Defendant.

54. Boston Scientific breached various warranties of merchantability with respect to Rezum in that it was improperly labeled, advertised, marketed, presented accurate seminar presentations, publications, notice letters, and regulatory submissions that the device was safe.

55. The Plaintiff relied upon the warranties of merchantability, and the device was used in the prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Boston Scientific.

56. Boston Scientific breached the warranties of merchantability to the Plaintiff, in that the device was not of merchantable quality, safe and fit for its intended use, was adequately tested in that the physicians who utilize the device were not properly trained or warned of the risks as set forth in MAUDE, that the devices posed.

57. As a result of a breach of the warranties of merchantability the Plaintiff suffered permanent serious injury.

COUNT VIII
STRICT LIABILITY PURSUANT TO THE RESTATEMENT OF TORTS

58. Plaintiffs hereby incorporate paragraphs 1 through 57 as if fully rewritten herein.

59. The Plaintiff utilized the Rezum delivery system in a manner for which it was intended.

60. The Rezum delivery system reached the Plaintiff without substantial change to its condition as manufactured, created, designed, tested, labeled, packaged, supplied, marketed, sold, advertised, and otherwise distributed by Boston Scientific

61. The Plaintiff was not aware and was not warned and reasonably could not have discovered the potential risks of the Rezum delivery system, including those risks gleaned by MAUDE.

62. The Rezum delivery system caused increased risk of excess tissue loss and nerve damage when used by Dr. Eltemamy. As a direct and proximate cause, the Plaintiff has suffered compensatory and punitive damages in an amount to be proven at trial.

63. It is believed and therefore averred, that Boston Scientific's conduct in failing to notify or to warn the Plaintiff or his Physicians of the risks involved with the Rezum delivery system constitutes ill will, bad motive, and reckless indifference to the interests of the consumers, including the Plaintiff. Consequently, the Plaintiff is entitled to punitive damages.

COUNT IX
VIOLATIONS OF OHIO CONSUMER PROTECTION STATUTE

64. Plaintiffs hereby incorporate paragraphs 1 through 63 as if fully rewritten herein.

65. The Plaintiff alleges that he is a consumer entitled to the protections of the Consumer Sales Practices Act, O.R.C. § 1345.01 et seq. and that he received treatment from the Rezum delivery system as manufactured, marketed and supplied by the Defendant.

66. The Defendant Boston Scientific, supplied Plaintiff's medical provider with the Rezum delivery system, and accordingly is a supplier in connection with the consumer transactions pursuant to O.R.C. § 1345.01 et seq.

67. The Defendant, Boston Scientific, deceived the Plaintiff in violation of O.R.C. §1345.02 (a) of the act by promoting, soliciting, effecting and/or allowing sales with the use of unfair, false, misleading or deceptive acts or practices to Plaintiff, either directly or indirectly through his medical provider.

68. The Defendant engaged in deceptive acts or practices in violation of O.R.C.§ 1345.02 (B)(2) as a supplier in connection with consumer transactions in that the Defendant knew at the time that the transactions were entered into that they deceptively withheld and actively represented that the Rezum delivery system was of a particular standard, quality grade or prescription and the physicians use of Rezum would require certified training.

69. Defendant engaged in unconscionable acts and practices pursuant to O.R.C. §1345.03(B)(6).

70. The Defendant knowingly accepted the benefits of its deception in the form of profits and increased sales.

71. The Defendant should have taken affirmative steps to warn consumers, including the Plaintiff, of the potential harm in utilizing the Rezum delivery system and those

risks set forth in MAUDE, particularly those risks associated with excess treatment.

72. As a direct and proximate cause of Defendants' deceptive and unconscionable acts and practices, Plaintiff has suffered irreparable personal injury.

73. Plaintiff further alleges that Defendant knowingly committed the acts and practices in violation of the Ohio Consumer Sales Practices and is accordingly responsible for attorney's fees and punitive damages.

COUNT X
STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

74. Plaintiffs hereby incorporate paragraphs 1 through 73 as if fully rewritten herein.

75. This count is for strict liability based on a manufacturing defect.

76. The Rezum delivery system was designed to provide treatments to people, including the plaintiff, who suffered from BPH. However, overtreatment causes excess tissue loss and/or nerve damage, resulting in catastrophic injury to the patient's ability to control urination, without a mechanism for preventing such injury.

77. The manufacturing defect utilized for treatment to the Plaintiff's prostate, caused serious damage to the plaintiff, including bodily injury, pain-and-suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the cost of medical care and expenses, all of which damages and losses will continue into the future for which the plaintiff demands judgment.

COUNT XI
STRICT PRODUCTS LIABILITY, FAILURE TO WARN

78. Plaintiffs hereby incorporate paragraphs 1 through 77 as if fully rewritten herein.

79. The Rezum delivery system utilized to treat Plaintiff's prostate contained no warnings or, in the alternative, inadequate warnings as to the risk that the product posed to the Plaintiff. Further, warnings could have and should have been added after Stryker became aware of the adverse events being suffered by other patients as a result of the utilization of the Rezum product.

80. The warnings that should have been provided to the Plaintiff and physicians that are utilizing the Rezum product would be a level of information that an ordinary consumer, including the Plaintiff, would expect when using the product in a manner reasonably foreseeable to the Defendant.

81. Further, the Rezum product left the Defendant's control without those warnings. When Boston Scientific became aware of adverse events, warnings to the physicians and others who might use the product should have been issued so it created an unreasonably dangerous condition when utilized on the Plaintiff. Alternatively, after the device left the defendant's control, defendants became aware of, or in the exercise of ordinary care should have known, that the Rezum delivery system posed a substantial risk of harm to patients, including the Plaintiff, yet Stryker failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances, which was a proximate cause of Plaintiff's injury and for which Plaintiffs seek relief.

COUNT XII
LOSS OF CONSORTIUM

82. Plaintiffs hereby incorporate paragraphs 1 through 81 as if fully rewritten herein.

83. Mrs. Stojanovic, Plaintiff's wife, has suffered damages, which include the loss of companionship, care, assistance, attention, protection, advice, counsel, guidance

and education. Mrs. Stojanovic also suffered severe mental anguish and emotional distress as a result of the injuries her husband has suffered.

COUNT XIII
EMOTIONAL DISTRESS

84. Plaintiffs hereby incorporate paragraphs 1 through 83 as if fully rewritten herein.

85. The Defendants, as a direct and proximate cause of the negligence herein set forth, have negligently inflicted and caused severe emotional distress to the Plaintiffs. Following the procedure, Mr. Stojanovic suffered frequent, multiple and chronic urinary tract infections, including sepsis, that has posed a direct risk to his transplanted kidney. The Plaintiffs have particularly and emotionally been plagued by the potential loss of kidney function because the chronic infections pose a direct threat to his kidney and kidney function. Every time Mr. Stojanovic stops taking anti-biotics, a urinary tract infection quickly develops, thus reducing his quality of life because he is persistently sick and having to admit himself to hospitals and emergency departments for more antibiotics, which are becoming increasingly resistant to the bacteria as a direct result of being repeatedly exposed to those antibiotics that are required to address the infections. Mr. Stojanovic never had a urinary tract infection prior to the cystoscopy with utilization of the Rezum delivery system.

WHEREFORE, Plaintiffs demand judgment against all Defendants, jointly and severally, for compensatory and punitive damages for Mr. Stojanovic injuries and the Plaintiffs emotional distress claims, in an amount in excess of Twenty-five Thousand Dollars ($25,000.00), plus interest, attorney fees, the costs of this action and for all other relief that this Court deems just and equitable.

Respectfully Submitted,

/s/ William A. Carlin
WILLIAM A. CARLIN 0009144
29325 Chagrin Blvd., Ste. 305
Pepper Pike, Ohio 44122
TEL: 216/831-4935;
FAX: 216/831-9526
WcarlinEsq@aol.com

JURY DEMAND

The Plaintiffs hereby demand a trial by jury on all issues herein.

/s/ William A. Carlin
William A. Carlin 0009144

AFFIDAVIT OF DR. DAVID CHAIKIN

STATE OF NEW JERSEY)
) S.S
COUNTY OF MORRIS)

Now comes Dr. David Chaikin and after first being duly sworn, deposes and states the following:

1. That he is licensed to practice medicine in the state of New Jersey;

2. That he reviewed all medical records that reasonably were made available to him as it pertains to the treatment and medical care of Veseljko Stojanovic was a patient at Cleveland Clinic, Cleveland, Ohio;

3. That the Affiant is familiar with the applicable standard of care that would pertain to the medical care that Veseljko Stojanovic received;

4. That Affiant is of the opinion that the standard of care was breached by Dr. Mohamed Eltemany at Cleveland Clinic and was a proximate cause of injuries sustained by Veseljko Stojanovic, while he was in his care at Cleveland Clinic.

AFFIANT SAYS NOTHING FURTHER.

Dr. David Chaikin

The foregoing was subscribed and sworn to before me by **Dr. David Chaikin,** this 11 day of May, 2022,

Brea Grosch
Notary

BREA GROSCH
Notary Public - State of New Jersey
My Commission Expires Aug 6, 2025

EXHIBIT A

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC, et al.,	)	CASE NO. CV 22 963537
	)	
Plaintiffs,	)	JUDGE ANDREW J. SANTOLI
	)	
vs.	)	**DEFENDANT MOHAMED ELTEMAMY, M.D.'S SEPARATE ANSWER TO PLAINTIFFS' COMPLAINT**
	)	
	)	
BOSTON SCIENTIFIC CORPORATION, et al.,	)	
	)	
	)	**(Jury Demand Endorsed Hereon)**
Defendants.	)	

Defendant, Mohamed Eltemamy, M.D. by and through counsel, and for his Separate Answer to Plaintiffs' Complaint, hereby states as follows:

ANSWER TO FACTS COMMON TO ALL COUNTS

1. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 1 of Plaintiffs' Complaint.

2. Defendant admits only that he rendered treatment and care to Plaintiff, Mr. Stojanovic while within the scope of his employment with the Cleveland Clinic Foundation. Further answering, Defendant neither admits nor denies the remaining averments and allegations set forth in Paragraph 2 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

3. Defendant denies for want of knowledge information, and otherwise, the averments and allegations set forth in Paragraph 3 of Plaintiffs' Complaint.

4. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 4 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

5. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 5 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

6. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 6 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

7. Defendant denies the averments and allegations set forth in Paragraph 7 of Plaintiffs' Complaint.

8. Defendant denies the averments and allegations set forth in Paragraph 8 of Plaintiffs' Complaint.

9. Defendant denies the averments and allegations set forth in Paragraph 9 of Plaintiffs' Complaint.

10. Defendant admits the averments and allegations set forth in Paragraph 10.

11. Defendant admits only that Dr. Eltemamy was acting within the course and scope of his employment with the Cleveland Clinic and denies as specifically stated the remaining averments and allegations set forth in Paragraph 11.

12. Defendant denies the averments and allegations set forth in Paragraph 12 of Plaintiffs' Complaint.

13. Defendant denies the averments and allegations set forth in Paragraph 13 of Plaintiffs' Complaint.

14. Defendant denies the averments and allegations set forth in Paragraph 14 of Plaintiffs' Complaint.

ANSWER TO COUNT I NEGLIGENCE

15. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 15 of Plaintiffs' Complaint.

16. Defendant denies the averments and allegations set forth in Paragraph 16 of Plaintiffs' Complaint.

ANSWER TO COUNT II RES IPSA LOQUITUR

17. Defendant incorporates the admissions and denials in the prior paragraphs in response to the paragraph incorporated into Paragraph 17 of Plaintiffs' Complaint.

18. Defendant denies the averments and allegations set forth in Paragraph 18 of Plaintiffs' Complaint.

ANSWER TO COUNT III

19. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 19 of Plaintiffs' Complaint.

20. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 20 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

21. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 21 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

22. Defendant denies the averments and allegations set forth in Paragraph 22 of Plaintiffs' Complaint.

23. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 23 of Plaintiffs' Complaint.

24. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 24 of Plaintiffs' Complaint.

25. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 25 of Plaintiffs' Complaint.

26. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 26 of Plaintiffs' Complaint.

27. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 27 of Plaintiffs' Complaint.

28. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 28 of Plaintiffs' Complaint.

29. Defendant neither denies nor admits the averments and allegations set forth in Paragraph 29 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

30. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 30 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

31. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 31 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

32. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 32 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

33. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 33 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

34. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 34 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

35. Defendant denies the averments and allegations set forth in Paragraph 35 of Plaintiffs' Complaint.

36. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 36 of Plaintiffs' Complaint.

37. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 37 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT IV NEGLIGENCE PER SE

38. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 38 of Plaintiffs' Complaint.

39. Defendant neither admits or denies the averments and allegations set forth in Paragraph 39 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

40. Defendant neither admits or denies the averments and allegations set forth in Paragraph 40 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT V BREACH OF EXPRESS WARRANTY

41. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 41 of Plaintiffs' Complaint.

42. Defendant neither admits or denies the averments and allegations set forth in Paragraph 42 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

43. Defendant neither admits or denies the averments and allegations set forth in Paragraph 43 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

44. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 44 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

45. Defendant neither admits or denies the averments and allegations set forth in Paragraph 45 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VI BREACH OF IMPLIED WARRANTY

46. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 46 of Plaintiffs' Complaint.

47. Defendant neither admits or denies the averments and allegations set forth in Paragraph 47 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

48. Defendant neither admits or denies the averments and allegations set forth in Paragraph 48 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VII BREACH OF WARRANTY AS TO MERCHANTABILITY

49. Defendant incorporates the admissions and denials in the prior paragraphs in 49 of Plaintiffs' Complaint Defendant.

50. Defendant neither admits or denies the averments and allegations set forth in Paragraph 50 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

51. Defendant neither admits or denies the averments and allegations set forth in Paragraph 51 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

52. Defendant neither admits or denies the averments and allegations set forth in Paragraph 52 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

53. Defendant neither admits or denies the averments and allegations set forth in Paragraph 53 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

54. Defendant neither admits or denies the averments and allegations set forth in Paragraph 54 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

55. Defendant neither admits or denies the averments and allegations set forth in Paragraph 55 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

56. Defendant neither admits or denies the averments and allegations set forth in Paragraph 56 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

57. Defendant neither admits or denies the averments and allegations set forth in Paragraph 57 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VIII STRICT LIABILITY PURSUANT TO THE RESTATEMENT OF TORTS

58. Defendant incorporates the admissions and denials in the prior paragraphs in 58 of Plaintiffs' Complaint Defendant.

59. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 59 of Plaintiffs' Complaint.

60. Defendant neither admits or denies the averments and allegations set forth in Paragraph 60 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

61. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 61 of Plaintiffs' Complaint.

62. Defendant denies the averments and allegations set forth in Paragraph 62 of Plaintiffs' Complaint.

63. Defendant denies the averments and allegations set forth in Paragraph 63 of Plaintiffs' Complaint.

ANSWER TO COUNT IX VIOLATIONS OF OHIO CONSUMER PROTECTION STATUTE

64. Defendant incorporates the admissions and denials in the prior paragraphs in 64 of Plaintiffs' Complaint Defendant.

65. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 65 of Plaintiffs' Complaint.

66. Defendant neither admits or denies the averments and allegations set forth in Paragraph 66 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

67. Defendant neither admits or denies the averments and allegations set forth in Paragraph 67 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

68. Defendant neither admits or denies the averments and allegations set forth in Paragraph 68 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

69. Defendant neither admits or denies the averments and allegations set forth in Paragraph 69 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

70. Defendant neither admits or denies the averments and allegations set forth in Paragraph 70 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

71. Defendant neither admits or denies the averments and allegations set forth in Paragraph 71 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

72. Defendant neither admits or denies the averments and allegations set forth in Paragraph 72 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

73. Defendant neither admits or denies the averments and allegations set forth in Paragraph 73 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT X STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

74. Defendant incorporates the admissions and denials in the prior paragraphs in 74 of Plaintiffs' Complaint Defendant.

75. Defendant neither admits or denies the averments and allegations set forth in Paragraph 75 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

76. Defendant neither admits or denies the averments and allegations set forth in Paragraph 76 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

77. Defendant neither admits or denies the averments and allegations set forth in Paragraph 77 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT XI STRICT PRODUCTS LIABILITY, FAILURE TO WARN

78. Defendant incorporates the admissions and denials in the prior paragraphs in 78 of Plaintiffs' Complaint Defendant.

79. Defendant neither admits or denies the averments and allegations set forth in Paragraph 79 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

80. Defendant neither admits or denies the averments and allegations set forth in Paragraph 80 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

81. Defendant neither admits or denies the averments and allegations set forth in Paragraph 81 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT XII LOSS OF CONSORTIUM

82. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 82 of Plaintiffs' Complaint.

83. Defendant denies the averments and allegations set forth in Paragraph 83 of Plaintiffs' Complaint.

ANSWER TO COUNT XIII EMOTIONAL DISTRESS

84. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 84 of Plaintiffs' Complaint.

85. Defendant denies the averments and allegations set forth in Paragraph 85 of Plaintiffs' Complaint. Further answering, Defendant denies the averments and allegations set forth in the unnumbered paragraph following Paragraph 85 of Plaintiffs' Complaint.

AFFIRMATIVE DEFENSES

1. Plaintiffs' Complaint fails to state a claim against this Defendant upon which relief can be granted.

2. Am. Sub. S.B. 281 and/or Am. Sub. S.B. 120 and/or S.B. 179, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiffs' claims.

3. All or part of Plaintiffs' Complaint is barred by the applicable statute of limitations, statute of repose and/or the doctrines of waiver, estoppel or laches.

4. Plaintiffs' claims against Defendant are barred by the legal doctrines of intervening and/or superseding cause.

5. If Plaintiffs suffered any of the alleged injuries, which are denied, such injuries were caused in whole or in part by the acts and/or omissions of third-parties over whose conduct Defendant had no control, right to control, responsibility or reason to anticipate.

6. If Plaintiffs sustained any of the injuries or damages alleged in the Complaint, such injuries and damages were caused, or were contributed to, by Plaintiffs' own comparative negligence, intentional acts, culpable conduct, and express or implied assumption of the risk. Such conduct serves as a bar to one or more of the claims alleged, and/or entitles Defendants to a reduction in damages pursuant to R.C. §2307.22, et seq. and R.C. §2315.32, et seq.

7. The injuries or damages of which Plaintiffs complain are attributable to one or more persons from whom Plaintiffs do not seek recovery in this action, and Plaintiffs have failed to join necessary and indispensable parties to this litigation.

8. Defendant hereby raises, asserts, and preserves its Rule 12(B)(1), 12(B)(2) and 12(B)(3) defenses of lack of jurisdiction over the subject matter, lack of jurisdiction over the person and improper venue.

9. Defendant hereby raises, asserts, and preserves its Rule 12(B)(4) and 12(B)(5) defenses of insufficiency of process and insufficiency of service of process, respectively.

10. The injuries and damages of which Plaintiffs complain were not under Defendant's control and can occur in the absence of negligence.

11. Plaintiffs' Complaint has not been properly served, and this action has not been properly commenced against Defendant, pursuant to Rules 3 and 15 of the Ohio Rules of Civil Procedure, therefore, Defendant raises, asserts and preserves all available Rule 3 and Rule 15 defenses.

12. Without prejudice to their denials and other assertions herein, Defendant states that the damages of which Plaintiffs complain were the proximate result of a totally unforeseeable disease or condition.

13. Plaintiffs were fully advised of the nature and extent of the treatment to be rendered and the material risks and dangers inherently and potentially involved therewith, as well as the alternatives available for treatment, and thereafter consented to the treatment rendered and assumed the risks that were clearly inherent in that treatment.

14. One or more of Plaintiffs' claims for damages are subject to the limits on certain types of damages, and this Court is without jurisdiction to enter judgment for Plaintiffs beyond the limitations set forth in O.R.C. §2323.43.

15. Plaintiffs lack a reasonable good faith basis to bring this medical claim, thereby entitling Defendant to an award of attorneys' fees and costs against Plaintiffs as provided by O.R.C. §2323.42.

16. Plaintiffs' Affidavit of Merit does not comply with the requirements of Rule 10(D)(2) of the Ohio Rules of Civil Procedure and, as a result, all or portions of Plaintiff's claim are barred. Defendant raises, asserts and preserves all available, applicable Rule 10 defenses.

17. Defendant states that if Plaintiffs suffered any of the injuries, losses and damages alleged in their Complaint, said injuries, losses and damages were a direct and proximate result of Plaintiffs' failure to mitigate their damages.

18. Plaintiffs' demand for punitive damages violates the Constitution and the laws of the United States and the State of Ohio.

19. Defendant hereby gives notice and intends to rely upon such other defenses as may become known during the course of discovery and hereby reserves the right to amend its Answer and to assert any such defense.

WHEREFORE, having fully answered Plaintiffs' Complaint, Defendant Cleveland Clinic Foundation requests that Plaintiffs' Complaint be denied and dismissed with prejudice and that Defendant be permitted to go henceforth without delay and with its costs.

JURY DEMAND

Pursuant to Rule 38(B) of the Ohio Rules of Civil Procedure, Defendant requests a trial by jury.

Respectfully submitted,

/s/Kris H. Treu

KRIS H. TREU, ESQ. (0013106)
MARY E. WHITE, ESQ. (0075856)
MOSCARINO & TREU LLP
The Hanna Building
1422 Euclid Avenue, Suite 630
Cleveland, Ohio 44115
Telephone: (216) 621-1000
Facsimile: (216) 574-4788
Email: ktreu@mosctreu.com
mwhite@mosctreu.com

Counsel for Defendants
Cleveland Clinic Foundation aka Cleveland Clinic and Mohamed Eltemamy, M.D.

CERTIFICATE OF SERVICE

The foregoing Separate Answer to Plaintiffs' Complaint has been sent via electronic mail this 18th day of July 2022 to:

William A. Carlin, Esq.
29325 Chagrin Blvd., Suite 305
Pepper Pike, OH 44122
Counsel for Plaintiffs

Sarah L. Bunce, Esq.
Nelson Mullins Riley & Scarborough LLP
1111 Superior Ave., Suite 530
Cleveland, OH 44114
Counsel for Defendant
Boston Scientific Corporation

/s/Kris H. Treu
KRIS H. TREU, ESQ.
MARY E. WHITE, ESQ.

Counsel for Defendants

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC, et al.,	)	CASE NO. CV 22 963537
	)	
Plaintiffs,	)	JUDGE ANDREW J. SANTOLI
	)	
vs.	)	**DEFENDANT THE CLEVELAND CLINIC FOUNDATION AKA CLEVELAND CLINIC'S SEPARATE ANSWER TO PLAINTIFFS' COMPLAINT**
BOSTON SCIENTIFIC CORPORATION, et al.,	)	
	)	**(Jury Demand Endorsed Hereon)**
Defendants.	)	

Defendant, Cleveland Clinic Foundation aka Cleveland Clinic, by and through counsel, and for its Separate Answer to Plaintiffs' Complaint, hereby states as follows:

ANSWER TO FACTS COMMON TO ALL COUNTS

1. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 1 of Plaintiffs' Complaint.

2. Defendant admits only that The Cleveland Clinic Foundation is a charitable organization, duly organized and existing under the laws of the State of Ohio to maintain facilities for the use of employed physicians and others in their care of the sick and injured and that Mohamed Eltemamy, M.D. is a Cleveland Clinic employee. Further answering, Defendant denies for want of knowledge information, and otherwise, the remaining averments and allegations set forth in Paragraph 2 of Plaintiffs' Complaint.

3. Defendant denies for want of knowledge information, and otherwise, the averments and allegations set forth in Paragraph 3 of Plaintiffs' Complaint.

4. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 4 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

5. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 5 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

6. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 6 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

7. Defendant denies the averments and allegations set forth in Paragraph 7 of Plaintiffs' Complaint.

8. Defendant denies the averments and allegations set forth in Paragraph 8 of Plaintiffs' Complaint.

9. Defendant denies the averments and allegations set forth in Paragraph 9 of Plaintiffs' Complaint.

10. Defendant admits the averments and allegations set forth in Paragraph 10.

11. Defendant admits only that Dr. Eltemamy was acting within the course and scope of his employment with the Cleveland Clinic and denies as specifically stated the remaining averments and allegations set forth in Paragraph 11.

12. Defendant denies the averments and allegations set forth in Paragraph 12 of Plaintiffs' Complaint.

13. Defendant denies the averments and allegations set forth in Paragraph 13 of Plaintiffs' Complaint.

14. Defendant denies the averments and allegations set forth in Paragraph 14 of Plaintiffs' Complaint.

ANSWER TO COUNT I NEGLIGENCE

15. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 15 of Plaintiffs' Complaint.

16. Defendant denies the averments and allegations set forth in Paragraph 16 of Plaintiffs' Complaint.

ANSWER TO COUNT II RES IPSA LOQUITUR

17. Defendant incorporates the admissions and denials in the prior paragraphs in response to the paragraph incorporated into Paragraph 17 of Plaintiffs' Complaint.

18. Defendant denies the averments and allegations set forth in Paragraph 18 of Plaintiffs' Complaint.

ANSWER TO COUNT III

19. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 19 of Plaintiffs' Complaint.

20. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 20 of Plaintiffs' Complaint.

21. Defendant denies the averments and allegations set forth in Paragraph 21 of Plaintiffs' Complaint.

22. Defendant denies the averments and allegations set forth in Paragraph 22 of Plaintiffs' Complaint.

23. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 23 of Plaintiffs' Complaint.

24. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 24 of Plaintiffs' Complaint.

25. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 25 of Plaintiffs' Complaint.

26. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 26 of Plaintiffs' Complaint.

27. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 27 of Plaintiffs' Complaint.

28. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 28 of Plaintiffs' Complaint.

29. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 29 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

30. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 30 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

31. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 31 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

32. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 32 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

33. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 33 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

34. Defendant neither admits nor denies the averments and allegations set forth in Paragraph 34 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

35. Defendant denies the averments and allegations set forth in Paragraph 35 of Plaintiffs' Complaint.

36. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 36 of Plaintiffs' Complaint.

37. Defendant neither admits or denies the averments and allegations set forth in Paragraph 37 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT IV NEGLIGENCE PER SE

38. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 38 of Plaintiffs' Complaint.

39. Defendant neither admits or denies the averments and allegations set forth in Paragraph 39 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

40. Defendant neither admits or denies the averments and allegations set forth in Paragraph 40 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT V BREACH OF EXPRESS WARRANTY

41. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 41 of Plaintiffs' Complaint.

42. Defendant neither admits or denies the averments and allegations set forth in Paragraph 42 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

43. Defendant neither admits or denies the averments and allegations set forth in Paragraph 43 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

44. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 43 of Plaintiffs' Complaint.

45. Defendant neither admits or denies the averments and allegations set forth in Paragraph 45 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VI BREACH OF IMPLIED WARRANTY

46. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 46 of Plaintiffs' Complaint.

47. Defendant neither admits or denies the averments and allegations set forth in Paragraph 47 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

48. Defendant neither admits or denies the averments and allegations set forth in Paragraph 48 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VII BREACH OF WARRANTY AS TO MERCHANTABILITY

49. Defendant incorporates the admissions and denials in the prior paragraphs in 49 of Plaintiffs' Complaint Defendant.

50. Defendant neither admits or denies the averments and allegations set forth in Paragraph 50 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

51. Defendant neither admits or denies the averments and allegations set forth in Paragraph 51 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

52. Defendant neither admits or denies the averments and allegations set forth in Paragraph 52 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

53. Defendant neither admits or denies the averments and allegations set forth in Paragraph 53 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

54. Defendant neither admits or denies the averments and allegations set forth in Paragraph 54 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

55. Defendant neither admits or denies the averments and allegations set forth in Paragraph 55 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

56. Defendant neither admits or denies the averments and allegations set forth in Paragraph 56 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

57. Defendant neither admits or denies the averments and allegations set forth in Paragraph 57 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT VIII STRICT LIABILITY PURSUANT TO THE RESTATEMENT OF TORTS

58. Defendant incorporates the admissions and denials in the prior paragraphs in 58 of Plaintiffs' Complaint Defendant.

59. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 59 of Plaintiffs' Complaint.

60. Defendant neither admits or denies the averments and allegations set forth in Paragraph 60 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

61. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 61 of Plaintiffs' Complaint.

62. Defendant denies the averments and allegations set forth in Paragraph 62 of Plaintiffs' Complaint.

63. Defendant denies the averments and allegations set forth in Paragraph 63 of Plaintiffs' Complaint.

ANSWER TO COUNT IX VIOLATIONS OF OHIO CONSUMER PROTECTION STATUTE

64. Defendant incorporates the admissions and denials in the prior paragraphs in 64 of Plaintiffs' Complaint Defendant.

65. Defendant denies for want of knowledge, information, and otherwise, the averments and allegations set forth in Paragraph 65 of Plaintiffs' Complaint.

66. Defendant neither admits or denies the averments and allegations set forth in Paragraph 66 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

67. Defendant neither admits or denies the averments and allegations set forth in Paragraph 67 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

68. Defendant neither admits or denies the averments and allegations set forth in Paragraph 68 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

69. Defendant neither admits or denies the averments and allegations set forth in Paragraph 69 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

70. Defendant neither admits or denies the averments and allegations set forth in Paragraph 70 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

71. Defendant neither admits or denies the averments and allegations set forth in Paragraph 71 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

72. Defendant neither admits or denies the averments and allegations set forth in Paragraph 72 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

73. Defendant neither admits or denies the averments and allegations set forth in Paragraph 73 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT X STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

74. Defendant incorporates the admissions and denials in the prior paragraphs in 74 of Plaintiffs' Complaint Defendant.

75. Defendant neither admits or denies the averments and allegations set forth in Paragraph 75 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

76. Defendant neither admits or denies the averments and allegations set forth in Paragraph 76 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

77. Defendant neither admits or denies the averments and allegations set forth in Paragraph 77 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT XI STRICT PRODUCTS LIABILITY, FAILURE TO WARN

78. Defendant incorporates the admissions and denials in the prior paragraphs in 78 of Plaintiffs' Complaint Defendant.

79. Defendant neither admits or denies the averments and allegations set forth in Paragraph 79 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

80. Defendant neither admits or denies the averments and allegations set forth in Paragraph 80 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

81. Defendant neither admits or denies the averments and allegations set forth in Paragraph 81 of Plaintiffs' Complaint as they are directed to a party other than this answering Defendant.

ANSWER TO COUNT XII LOSS OF CONSORTIUM

82. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 82 of Plaintiffs' Complaint.

83. Defendant denies the averments and allegations set forth in Paragraph 83 of Plaintiffs' Complaint.

ANSWER TO COUNT XIII EMOTIONAL DISTRESS

84. Defendant incorporates the admissions and denials in the prior paragraphs in response to Paragraph 84 of Plaintiffs' Complaint.

85. Defendant denies the averments and allegations set forth in Paragraph 85 of of Plaintiffs' Complaint. Further answering, Defendant denies the averments and allegations set forth in the unnumbered paragraph following Paragraph 85 of Plaintiffs' Complaint.

AFFIRMATIVE DEFENSES

1. Plaintiffs' Complaint fails to state a claim against this Defendant upon which relief can be granted.

2. Am. Sub. S.B. 281 and/or Am. Sub. S.B. 120 and/or S.B. 179, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiffs' claims.

3. All or part of Plaintiffs' Complaint is barred by the applicable statute of limitations, statute of repose and/or the doctrines of waiver, estoppel or laches.

4. Plaintiffs' claims against Defendant are barred by the legal doctrines of intervening and/or superseding cause.

5. If Plaintiffs suffered any of the alleged injuries, which are denied, such injuries were caused in whole or in part by the acts and/or omissions of third-parties over whose conduct Defendant had no control, right to control, responsibility or reason to anticipate.

6. If Plaintiffs sustained any of the injuries or damages alleged in the Complaint, such injuries and damages were caused, or were contributed to, by Plaintiffs' own comparative negligence, intentional acts, culpable conduct, and express or implied assumption of the risk. Such conduct serves as a bar to one or more of the claims alleged, and/or entitles Defendants to a reduction in damages pursuant to R.C. §2307.22, et seq. and R.C. §2315.32, et seq.

7. The injuries or damages of which Plaintiffs complain are attributable to one or more persons from whom Plaintiffs do not seek recovery in this action, and Plaintiffs have failed to join necessary and indispensable parties to this litigation.

8. Defendant hereby raises, asserts, and preserves its Rule 12(B)(1), 12(B)(2) and 12(B)(3) defenses of lack of jurisdiction over the subject matter, lack of jurisdiction over the person and improper venue.

9. The injuries and damages of which Plaintiffs complain were not under Defendant's control and can occur in the absence of negligence.

10. Defendant hereby raises, asserts, and preserves its Rule 12(B)(4) and 12(B)(5) defenses of insufficiency of process and insufficiency of service of process, respectively.

11. Plaintiffs' Complaint has not been properly served, and this action has not been properly commenced against Defendant, pursuant to Rules 3 and 15 of the Ohio Rules of Civil Procedure, therefore, Defendant raises, asserts, and preserves all available Rule 3 and Rule 15 defenses.

12. Without prejudice to their denials and other assertions herein, Defendant states that the damages of which Plaintiffs complain were the proximate result of a totally unforeseeable disease or condition.

13. Plaintiffs were fully advised of the nature and extent of the treatment to be rendered and the material risks and dangers inherently and potentially involved therewith, as well as the alternatives available for treatment, and thereafter consented to the treatment rendered and assumed the risks that were clearly inherent in that treatment.

14. One or more of Plaintiffs' claims for damages are subject to the limits on certain types of damages, and this Court is without jurisdiction to enter judgment for Plaintiffs beyond the limitations set forth in O.R.C. §2323.43.

15. Plaintiffs lack a reasonable good faith basis to bring this medical claim, thereby entitling Defendant to an award of attorneys' fees and costs against Plaintiffs as provided by O.R.C. §2323.42.

16. Plaintiffs' Affidavit of Merit does not comply with the requirements of Rule 10(D)(2) of the Ohio Rules of Civil Procedure and, as a result, all or portions of Plaintiff's claim are barred. Defendant raises, asserts, and preserves all available, applicable Rule 10 defenses.

17. Defendant states that if Plaintiffs suffered any of the injuries, losses and damages alleged in their Complaint, said injuries, losses and damages were a direct and proximate result of Plaintiffs' failure to mitigate their damages.

18. Plaintiffs' demand for punitive damages violates the Constitution and the laws of the United States and the State of Ohio.

19. Defendant hereby gives notice and intends to rely upon such other defenses as may become known during the course of discovery and hereby reserves the right to amend its Answer and to assert any such defense.

WHEREFORE, having fully answered Plaintiffs' Complaint, Defendant Cleveland Clinic Foundation requests that Plaintiffs' Complaint be denied and dismissed with prejudice and that Defendant be permitted to go henceforth without delay and with its costs.

JURY DEMAND

Pursuant to Rule 38(B) of the Ohio Rules of Civil Procedure, Defendant requests a trial by jury.

Respectfully submitted,

/s/Kris H. Treu

KRIS H. TREU, ESQ. (0013106)
MARY E. WHITE, ESQ. (0075856)
MOSCARINO & TREU LLP
The Hanna Building
1422 Euclid Avenue, Suite 630
Cleveland, Ohio 44115
Telephone: (216) 621-1000
Facsimile: (216) 574-4788
Email: ktreu@mosctreu.com
mwhite@mosctreu.com

Counsel for Defendants
Cleveland Clinic Foundation aka Cleveland Clinic and Mohamed Eltemamy, M.D.

CERTIFICATE OF SERVICE

The foregoing Separate Answer to Plaintiffs' Complaint has been sent via electronic mail this 18th day of July 2022 to:

William A. Carlin, Esq.
29325 Chagrin Blvd., Suite 305
Pepper Pike, OH 44122
Counsel for Plaintiffs

Sarah L. Bunce, Esq.
Nelson Mullins Riley & Scarborough LLP
1111 Superior Ave., Suite 530
Cleveland, OH 44114
Counsel for Defendant
Boston Scientific Corporation

/s/Kris H. Treu
KRIS H. TREU, ESQ.
MARY E. WHITE, ESQ.

Counsel for Defendants

Motion No. 5017454

NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

MOTION TO DISMISS
June 24, 2022 15:47

By: SARAH L. BUNCE 0080816

Confirmation Nbr. 2585528

VESELJKO STOJANOVIC, ET AL

vs.

BOSTON SCIENTIFIC CORPORATION, ET AL

CV 22 963537

Judge: ANDREW J. SANTOLI

Pages Filed: 12

COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC et al., Plaintiffs, vs. BOSTON SCIENTIFIC CORPORATION et al., Defendants.	)	Civil Action No. CV-22-963537 **DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS**

Defendant Boston Scientific Corporation ("Boston Scientific"), by and through its undersigned attorneys, and pursuant to Ohio Rule of Civil Procedure 12(B)(6), respectfully requests that the Court dismiss Plaintiffs' Complaint because it fails to adequately state a cause of action for which relief may be granted. First, Plaintiffs' negligence, warranty, strict liability, OCSPA, and emotional distress claims are abrogated by the Ohio Products Liability Act ("OPLA") (Counts I, IV, V, VI, VII, VIII, IX, X, XI, and XIII). Second, res ipsa loquitur is not a cause of action, but a rule of evidence (Count II). Third, Plaintiffs' unidentified cause of action is an improper attempt to seek private relief under the FDCA (Count III). And finally, the loss-of-consortium claim is derivative of the foregoing faulty claims (Count XII) and therefore must likewise be dismissed.

In support of its Motion to Dismiss, Boston Scientific relies upon the attached Memorandum of Law.

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/s/ Sarah L. Bunce

Sarah L. Bunce
Bar Number 0080816
Attorney for Defendant Boston Scientific Corporation
Nelson Mullins Riley & Scarborough LLP
1111 Superior Ave., Suite 530
Cleveland, OH 44114
Tel: 216.304.6171
Email: sarah.bunce@nelsonmullins.com
Fax: 216.553.4275

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

INTRODUCTION

Plaintiffs' product-liability lawsuit strays far from well-established Ohio law—asserting unrecognized and abrogated claims and ignoring pleading standards meant to give Boston Scientific meaningful notice of the claims. All that Boston Scientific can factually discern from the pleadings is that Plaintiffs blame multiple parties for complications from a procedure where Boston Scientific's medical device was allegedly used. Legally, Boston Scientific can discern even less: Plaintiffs' causes of action range from wholly unidentified to trying to twist rules of evidence into independent claims. This haphazard approach is not sufficient to support Plaintiffs' ***thirteen*** causes of action. Boston Scientific should not have to struggle to understand what this lawsuit is about—factually or legally—and therefore respectfully requests the Court dismiss this Complaint.

BACKGROUND

Buried in Plaintiffs' 85-paragraph Complaint are just three paragraphs scarcely describing the subject procedure and injuries:

- Plaintiff Veseljko Stojanovic, an Ohio resident, underwent a cystoscopy procedure on June 2, 2021 to treat his benign prostatic hyperplasia;
- During the surgery, the "Rezum delivery system", manufactured by Boston Scientific, was used by Dr. Eltemamy; and
- Following the surgery, Mr. Stojanovic has been unable to control his ability to urinate and he has had to undergo further medical procedures.

(Complaint, ¶¶ 7-9.) Plaintiffs provide no other facts—such as how the Rezum device was defective or how it caused his alleged injury.

Based on these scant allegations, Plaintiffs filed a lawsuit seemingly asserting any cause of action they could think of (irrespective of Ohio law):

- **Count I** – Negligence (against all defendants);
- **Count II** – Res Ipsa Loquitur (Plaintiffs do not say which Defendants this claim is filed against);
- **Count III** – Plaintiffs do not state what this claim even is, and the averments do not shed any light (against Boston Scientific);
- **Count IV** – Negligence Per Se (against Boston Scientific);
- **Count V** – Breach of Express Warranty (against Boston Scientific);
- **Count VI** – Breach of Implied Warranty (against Boston Scientific);
- **Count VII** – Breach of Warranty as to Merchantability (against Boston Scientific);
- **Count VIII** – Strict Liability Pursuant to Restatement of Torts (against Boston Scientific);
- **Count IX** – Violations of Ohio Consumer Protection Statute ("OCPSA") (against Boston Scientific);
- **Count X** – Strict Products Liability, Manufacturing Defect (against Boston Scientific);
- **Count XI** – Strict Products Liability, Failure to Warn (against Boston Scientific);
- **Count XII** – Loss of Consortium (against all defendants);
- **Count XIII** – Emotional Distress (against all defendants).

Because these thirteen claims fail as a matter of law as against Boston Scientific, Boston Scientific brings this motion to dismiss.

LEGAL STANDARD

Ohio is a notice-pleading state, where Plaintiffs are required to plead "sufficient, operative facts to support recovery under his claims." *Allstate Ins. Co. v. Electrolux Home Prods., Inc.*, 8th Dist. Cuyahoga No. 97065, 2012-Ohio-90, ¶ 8. But while Plaintiffs need not plead operative facts with particularity, "to constitute fair notice, the complaint must allege sufficient underlying facts that relate to and support the alleged claim; the complaint may not simply state legal conclusions." *Id.* Indeed, while *factual* allegations are taken as true, "[u]nsupported conclusions of a complaint are not considered admitted" and "are not sufficient to withstand a motion to dismiss." *Saks v. E. Ohio Gas Co.*, 2012-Ohio-2637, 971 N.E.2d 498, ¶ 7 (8th Dist.). Thus, "[l]egal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness." *Williams v. U.S. Bank Shaker Square*, 8th Dist. Cuyahoga No. 89760, 2008-Ohio-1414, ¶ 9. Failure to plead a complaint in a manner providing sufficient notice warrants dismissal under Civ. R. 12(B)(6).

ARGUMENT

Despite asserting *thirteen* causes of action against Boston Scientific, Plaintiffs manage to not adequately plead a single cause of action. Each fails as a matter of law: (1) Plaintiffs' negligence, warranty, strict liability, OCSPA, and emotional distress claims are abrogated by the Ohio Products Liability Act ("OPLA") (Counts I, IV, V, VI, VII, VIII, IX, X, XI, and XIII); (2) res ipsa loquitur is not a cause of action, but a rule of evidence (Count II); (3) Plaintiffs' unidentified cause of action is an improper attempt to seek private relief under the FDCA (Count III); and (4) the loss-of-consortium claim is derivative of the foregoing faulty claims (Count XII).

I. PLAINTIFFS' NEGLIGENCE, WARRANTY, STRICT LIABILITY AND OCSPA CLAIMS ARE ABROGATED BY THE OPLA.

The OPLA governs all product liability causes of action, which are claims seeking "compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question" for:

> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
>
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
>
> (c) Any failure of that product to conform to any relevant representation or warranty.

R.C. 2307.71(A)(13). The OPLA expressly abrogates "all common law product liability claims or causes of action." R.C. 2307.71(B). Courts have similarly determined that non-OPLA statutory claims primarily rooted in product liability claims are also abrogated because holding otherwise "would basically provide [plaintiffs] with a separate statutory theory of recovery in a products liability case that is precluded under Ohio law." *Blake v. Interneuron Pharmaceuticals*, S.D.Ohio No. C-1-98-672, 1998 WL 35307753, *1 (Dec. 9, 1998).

Here, Plaintiffs' causes of actions for negligence (Count I), negligence per se (Count IV), breach of express warranty (Count V), breach of implied warranty (Count VI), breach of warranty as to merchantability (Count VII), strict liability (Counts VIII, X, and XII), OCSPA violations (Count IX), and emotional distress (Count XIII) are all unequivocally abrogated by the OPLA and must be dismissed. *See Harris v. Eli Lilly & Co.*, N.D.Ohio No. 4:12CV2481, 2012 WL 6732725, *3 (Dec. 28, 2012) ("It is clear from the law above that [Plaintiffs]' common law claims of strict

liability, negligence, breach of implied warranty, breach of express warranty, and violation of consumer protection statutes must be dismissed as abrogated by the OPLA").[1]

Moreover, even if any of these claims were intended to be pleaded under the OPLA (they clearly are not), they are nonetheless deficient. Ohio courts demand OPLA claims include references to the OPLA. *Harris v. Eli Lilly & Co.*, N.D.Ohio No. 4:12CV2481, 2012 WL 6732725, *4 (Dec. 28, 2012) ("Without some reference to the governing statute and its requirements, these [potential OPLA] claims cannot be defended."); *Stratford v. SmithKline Beecham Corp.*, S.D.Ohio No. 2:07-CV-639, 2008 WL 2491965, *5 (June 17, 2008) ("Claims that are authorized by the OPLA should be pled with reference to the applicable provision of the OPLA."). Failure to do so warrants dismissal—Boston Scientific is not on notice of what provision of the OPLA Plaintiffs are pursuing without adequate reference to them. *See Favor v. W.L. Gore Assoc., Inc.*, S.D.Ohio No. 2:13-CV-655, 2014 WL 533804, *6 (Feb. 11, 2014) ("[A] court should dismiss common law product liability claims that are pleaded without reference to the OPLA.").

II. RES IPSA LOQUITUR IS NOT A SUBSTANTIVE CAUSE OF ACTION

Plaintiffs' Count II asserts a cause of action for res ipsa loquitur. But the doctrine of res ipsa loquitor is merely "an evidentiary ruling permitting a trier of fact to draw an inference of negligence and ***is not a separate cause of action***." (Emphasis added.) *Douglas v. Columbus City*

[1] *See also Michelson v. Volkswagen Aktiengesellschaft*, 2018-Ohio-1303, 99 N.E.3d 475, ¶ 28 (8th Dist.) (granting motion to dismiss negligence claim because it was abrogated by the OPLA, and collecting cases that have done the same); *Boroff v. Alza Corp.*, 685 F.Supp.2d 704, 711 (N.D.Ohio 2010) (finding that the OPLA abrogates common law claims of breach of express warranty, negligence, and negligence per se); *Miller v. ALZA Corp.*, 759 F.Supp.2d 929, 943 (S.D.Ohio 2010) ("[C]ommon law warranty claims have also been abrogated by the OPLA" and granting summary judgment against warranty claims); *Utz v. Howmedica Osteonics, Corp.*, N.D.Ohio No. 1:06 CV 1963, 2008 WL 11378848, *4 (Sept. 19, 2008) (granting motion to dismiss to emotional-distress claim because it is abrogated by the OPLA); *Bouchard v. Am. Home Prods. Corp.*, N.D. Ohio No. 3:98 CV 7541, 2002 WL 32597992, at *11 (May 24, 2002) (granting motion for summary judgment on OCSPA claim because it was abrogated by the OPLA).

Schools Bd. of Edn., 2020-Ohio-1133, 152 N.E.3d 1245, ¶ 45 (10th Dist.); *see also Kniskern v. Twp. of Somerford*, 112 Ohio App.3d 189, 198, 678 N.E.2d 273 (10th Dist.1996) ("The doctrine of *res ipsa loquitor* is not a theory of tort liability; rather it is the doctrine of evidence which permits a plaintiff to prove negligence circumstantially."). Thus, courts routinely dismiss claims for res ipsa loquitur. *See, e.g.*, *Douglas*, 2020-Ohio-1133, 152 N.E.3d at ¶ 45 (affirming summary judgment against claim for liability under the doctrine of res ipsa loquitur); *Brown v. Dayton*, 2nd Dist. Montgomery No. 21542, 2006-Ohio-6816, ¶ 8 (affirming trial court's dismissal of claim for res ipsa loquitur because "res ipsa loquitur is not a cause of action but rather a rule of evidence").

Because Plaintiffs' claim for res ipsa loquitur is not a recognized cause of action under Ohio law, Boston Scientific respectfully requests the Court dismiss this claim.[2]

III. PLAINTIFFS' UNIDENTIFIED COUNT III IS AN IMPROPER ATTEMPT TO SEEK PRIVATE RELIEF UNDER THE FDCA.

Unlike every other cause of action, Plaintiffs did not identify the cause of action for Count III. *Generously* interpreting this claim, Plaintiffs take issue with Boston Scientific for not complying with various provisions of the FDA's Food Device Cosmetic Act ("FDCA"). (Complaint, ¶¶ 20-27.) But "[i]t is well-settled that ***there is no private right of action under the FDCA***." (Emphasis added.) *Edwards v. Warner-Lambert*, S.D. Ohio No. 2:05-CV-657, 2012 WL 2156246, at *4 (June 13, 2012); *see also Renfro v. Smith Laboratories, Inc.*, 6th Dist. Sandusky No. S-87-33, 1988 WL 134233 ("not[ing] that there exists no private cause of action for monetary recovery based upon alleged violation of the Federal Food, Drug and Cosmetic Act"), *6, *aff'd sub nom. Renfro v. Black*, 52 Ohio St.3d 27, 556 N.E.2d 150 (1990); 21 U.S.C. 337(a) ("proceedings for enforcement of the FDCA shall be by and in the name of the United

[2] Even if res ipsa loquitur were an independent cause of action, it would be abrogated by the OPLA, as explained above in Section I.

States"). As the United States Supreme Court has explained, the "FDCA leaves no doubt that it is the Federal Government rather than litigants who [is] authorized to file suit for noncompliance with the FDCA." *Buckman v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), fn. 4 (alteration in original). Plainly put, it is the FDA's role to enforce the FDCA, Plaintiffs cannot usurp it.

Because Plaintiffs' unidentified Count III appears to seek relief for FDCA violations—which is not a cognizable cause of action—Boston Scientific respectfully requests the Court dismiss this claim.[3]

IV. PLAINTIFFS' LOSS-OF-CONSORTIUM CLAIM IS DERIVATIVE OF THEIR LEGALLY-DEFICIENT CAUSES OF ACTION.

Claims for loss of consortium are "joint and inseparable" from the underlying tort claims—if those underlying claims fail, so must the loss-of-consortium claim. *Fehrenbach v. O'Malley*, 113 Ohio St.3d 18, 2007-Ohio-971, 862 N.E.2d 489, ¶ 21. In every sense of the word, loss-of-consortium claims are "derivative" of the underlying claims. *McCarthy v. Lee*, 10th Dist. Franklin No. 21AP-426, 2022-Ohio-1413, ¶ 10. Because Plaintiffs' twelve other causes of action must be dismissed as against Boston Scientific, this claim must also be dismissed. *Id.* (affirming dismissal of "derivative" loss-of-consortium claim where the underlying "principal" claim was dismissed).

CONCLUSION

For the foregoing reasons, Boston Scientific respectfully requests the Court dismiss all of Plaintiffs' claims against Boston Scientific with prejudice. Moreover, because of the high number of

[3] Even if there were a cause of action for violations of the FDCA (there is not), it would be abrogated by the OLPA. Plaintiffs' Count III allegations may be framed in a manner as seeking relief for FDCA violations, but they are nonetheless allegations concerning a defective product (through its manufacture, design, or warnings). This nonexistent claim would fall within the scope of the OPLA and would be abrogated. *See* R.C. 2307.71(A)(13) (setting forth scope of the OPLA).

claims—all of which are pleaded improperly—Boston Scientific summarizes the grounds for dismissal for each claim:

Count	Cause of Action	Reason for Dismissal
I	Negligence	Abrogated by the OPLA
II	Res Ipsa Loquitur	Not a recognized cause of action or abrogated by the OPLA
III	*Unknown*	Either an improper attempt to seek a private relief under the FDCA or abrogated by the OPLA
IV	Negligence Per Se	Abrogated by the OPLA
V	Breach of Express Warranty	Abrogated by the OPLA
VI	Breach of Implied Warranty	Abrogated by the OPLA
VII	Breach of Warranty as to Merchantability	Abrogated by the OPLA
VIII	Strict Liability Pursuant to Restatement of Torts	Abrogated by the OPLA
IX	Violations of Ohio Consumer Protection Statute	Abrogated by the OPLA
X	Strict Products Liability, Manufacturing Defect	Abrogated by the OPLA
XI	Strict Products Liability, Failure to Warn	Abrogated by the OPLA
XII	Loss of Consortium	Derivative of improperly pleaded claims
XIII	Emotional Distress	Abrogated by the OPLA

/s/ Sarah L. Bunce

Sarah L. Bunce
Bar Number 0080816
Attorney for Defendant Boston Scientific Corporation
Nelson Mullins Riley & Scarborough LLP
1111 Superior Ave., Suite 530
Cleveland, OH 44114
Tel: 216.304.6171
Email: sarah.bunce@nelsonmullins.com
Fax: 216.553.4275

CERTIFICATE OF SERVICE

A copy of the foregoing Defendant Boston Scientific Corporation's Motion to Dismiss was filed electronically on June 24, 2022. Service of this filing will be sent pursuant to Civil Rule 5(B)(2)(f) by operation of the Court's electronic filing system to all parties indicated on the system's e-mail filing confirmation to the following counsel of record:

William A. Carlin
29235 Chagrin Blvd., Suite 305
Cleveland, OH 44122
Counsel for Plaintiff

Kris H. Treu
Mary E. White
The Hanna Building
1422 Euclid Avenue, Suite 630
Cleveland, OH 44115
Counsel for Defendants Cleveland Clinic Foundation
and Mohamed Eltemamy, M.D.

/s/ Sarah L. Bunce

NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

BRIEF IN OPPOSITION
July 31, 2022 16:49

By: WILLIAM A. CARLIN 0009144

Confirmation Nbr. 2615089

VESELJKO STOJANOVIC, ET AL

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IN COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC, et al.	:	CASE NO: CV-22-963537
Plaintiffs	:	JUDGE: ANDREW J. SANTOLI
Vs.	:	
BOSTON SCIENTIFIC CORPORATION	:	
Defendants	:	

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

The Defendant, Boston Scientific Corporation ("BS") has filed an ill-conceived Motion to Dismiss Plaintiffs' Complaint. Plaintiffs' responds as follows:

While the Plaintiffs appreciate the advanced sampling of what is to come, the only relevant facts, right now, are those facts contained in the Complaint. BS has set forth the wrong standard for a Motion to Dismiss in Ohio Courts. BS is primarily relying upon Federal District trial court cases that support the code pleading standards set forth by the United States Supreme Court in *Twombly* and its progeny. BS argues that the claims within Plaintiffs' Complaint are required to make specific reference to statutory provisions that are invoked by the Plaintiffs. This is incorrect. BS states that the Ohio Consumer Sales Practices Act ("OCSPA") and emotional distress damage claims were abrogated by the Ohio Product Liability Act ("OPLA"). This is incorrect.

The Plaintiffs' Complaint references the United States Food and Drug Administration ("F. D. A") regulations, which promulgates mandatory regulations that manufacturers of medical

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devices are required to comply with. BS claims those F.D.A regulations cannot be utilized as an evidentiary basis in support of Plaintiffs' various causes of action. This is incorrect. BS states that Res Ipsa Loquitur has been abrogated by the OPLA. This is incorrect. BS states that the Plaintiffs' causes of action are not rooted in the OPLA. This is incorrect. BS has placed inordinate and misdirected emphasis on the count captions in Plaintiffs' Complaint. As the Ohio Supreme Court and Appellate Courts have cautioned; look to the "substance" of the Complaint, not the "captions". As demonstrated below each cause of action incorporates from the OPLA, including R. C. § 2307.76, R. C. § 2307.77, and R. C. § 2307.74.

FACTS AND BACKGROUND

BS alleges the Plaintiffs' "blame(s) multiple parties" for Plaintiff's injuries. Actually, Plaintiff alleges tortfeasors either in tandem and/or in the alternative, caused his injuries. BS essentially blames the surgical procedure for Plaintiff's injuries and the parties will have an opportunity to test that proposition when Dr. Eltemamy's deposition is taken. BS further claims that they are not being given meaningful notice of the claims. In that regard, their first argument is that the Complaint, "scarcely" describes the subject procedure and injuries. The Defendants are relying on the code pleading requirements of Federal Courts but "scarcely" still complies with the notice requirements of the Ohio Civil Rules. BS had enough information to state the facts exactly as they are; The Plaintiff underwent a cystoscopy procedure to treat benign prostatic hyperplasia. ("BPH"). The Rezum Delivery System, ("Rezum") manufactured by BS was used in the procedure, it was defective and the Complaint states that the Plaintiff sustained a permanent injury regarding a bodily organ. The Plaintiff further states at paragraph 5 of Plaintiffs' Complaint ("P-5") that BS is the manufacturer and distributor of the Rezum medical device that caused or contributed to the injury and that their medical device was marketed in Ohio.

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INTRODUCTION

DEFENDANT'S MOTION SHOULD BE DENIED AS IT IS NOT BASED ON THE PROPER CIV. R. 12(B)(6) STANDARD

As stated by the Ohio Supreme Court:

> In order for a trial court to dismiss a complaint under Civ. R. 12(B)(6) for failure to state a claim upon which relief can be granted, it must appear beyond doubt that the plaintiff can prove no set of facts in support of the claim that would entitle the plaintiff to the relief sought. The allegations of the complaint must be taken as true, and those allegations and any reasonable inferences drawn from them must be construed in the nonmoving party's favor.

Ohio Bur. Of Workers' Comp. v. Mckinley, 130 Ohio St.3d 156, 2011-Ohio-4432, 956 N.E.2d 814,

¶ 12.

Moreover, according to the Eighth District Court of Appeals:

> When discussing Ohio's pleading standard, this court has stated in the past that "'few complaints fail to meet the liberal [pleading] standards of Rule 8 and become subject to dismissal,' " and that "'the motion to dismiss is viewed with disfavor and should rarely be granted.'" *Id.* at ¶ 15, quoting *Slife v. Kundtz Properties, Inc.,* 40 Ohio App.2d 179, 182, 318 N.E.2d 557 (8th Dist.1974). When reviewing a complaint for failure to state a claim under 12(B)(6), "[t]he allegations of the complaint must be taken as true, and those allegations and *any reasonable inferences* drawn from them must be construed in the nonmoving party's favor." (Emphasis added.) *Antoon v. Cleveland Clinic Found.,* 8th Dist. Cuyahoga No. 101373, 2015-Ohio-421, ¶ 7.

Smiley v. Cleveland, 8th Dist. Cuyahoga No. 103987, 2016-Ohio-7711, 2016 WL 6673178, ¶ 6 (Nov. 10, 2016).

The Defendants are essentially attempting to have this case dismissed based on the heightened federal pleading requirements even though they claim they are not doing so. The heightened federal pleading requirements set forth by the U.S. Supreme Court in *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 S.Ct. 1955, 1964, 167 L.Ed.2d 929 (2007), to support the contention that "a cause of action in a complaint must be 'plausible' rather than merely 'conceivable.'" That case dealt exclusively with the interpretation and application of Fed. R.

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Civ. R. 12(b)(6) as opposed to Ohio Civ. R. 12(B)(6).

Further, the federal standard becomes even more glaring in light of several state court decisions specifically holding that Ohio has not adopted the heightened federal pleading standard. For example, the Eighth District explained:

> Abandoning nearly 40 years of routine standards that have been applied in this state should be a matter for the Ohio Supreme Court. *See Sacksteder*, 2d Dist. Montgomery No. 24993, 2012-Ohio-4452, 2012 WL 4480695, at ¶ 106 (Fain. J., concurring)(the decisions of *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal* "cannot override the rules of pleading established by the Ohio Rules of Civil Procedure, as interpreted by the Supreme Court of Ohio"; "[t]he Twombly line of cases has no application to the rules of pleading in Ohio courts unless and until the Supreme Court of Ohio incorporates the principles set forth in those cases in its interpretation of the Ohio rules of pleading."). Thus, until the Ohio Supreme Court adopts a new pleading standard or the Ohio Rules of Civil Procedure are changed, Ohio remains a notice-pleading state.

Tuleta v. Med. Mut. Ohio, 2014-Ohio-396, 6 N.E.3d 106, ¶ 31 (8th Dist.) *See also, Twombly. Smiley v. Cleveland,* 8th Dist. No. 103987, 2016-Ohio-7711, 2016 WL 6673178, ¶5. Therefore, the standard on which Plaintiff's Motion to Dismiss should be premised is on Ohio Law.

I. PLAINTIFFS CLAIMS DO NOT REQUIRE A SPECIFIC REFERENCE TO STATUTORY PROVISIONS UNDER THE OHIO PRODUCTS LIABILITY ACT

Generally, Plaintiffs Complaints set forth in State and Federal District Court cases often utilize a procedure where the Plaintiff, "will incorporate paragraphs ___ through ____ as if fully restated," at various places in the body of the complaint to reduce verbosity and paper, which is in compliance with notice pleading. Consequently, in some ways a complaint resembles a jury instruction in that you cannot embody all the claims in any single part of the complaint and you have to consider the complaint in light of and in harmony with all other sections of the complaint.

For some inconceivable reason, BS places a misdirected emphasis on the count captions.

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They argue the meaning and extrapolated content of case captions at the beginning, middle, and end of their Motion to Dismiss. The Ohio Courts have repeatedly cautioned against this as follows:

> *4{ ¶23} Moreover, the caption on Granite City's first claim stating "wrongful demolition" is not controlling. In construing a complaint, we look to the substance of the complaint, not the caption, to determine the nature of the cause being pleaded. *Funk v. Rent-All Mart, Inc.*, 91 Ohio St.3d 78, 80, 742 N.E.2d 127 (2001). We cannot say that it appears beyond doubt that Granite City can prove no set of facts entitling it to recovery. *O'Brien* at syllabus.

Granite City Center, LLC v. Board of Trustees of Champion Township, Slip Copy (2021) 2021-Ohio-1458.

In BS's first argument, BS exclusively cites Federal District Court cases, including *Harris v. Eli Lilly & Co.,* N.D. Ohio No. 4:12 CV 2481, 2012 WL 6732725*3 (2012) which represents an example of BS's citation to district court cases that rely on *Twombly* and federal code pleading. The Plaintiffs agrees that certain common law claims were abrogated by the Ohio Products Liability Act ("OPLA") which essentially incorporates those common law claims into the act itself. A pre OPLA complaint resembles and is often identical to a post OPLA complaint. The common law products liability concepts have been assimilated into OPLA. Cases pre OPLA are often favorably cited in post OPLA cases.

In further support of Plaintiffs' contention that BS is relying on federal code pleading requirements, BS cites *Blake v. Interneuron Pharmaceuticals, et al* S.D. Ohio No. C-1-98-672, 1998 WL 35307753*1 (1998). *Blake* is an unreported case from the United States District Court which examined a Motion to Dismiss. The motion was not responded to by the Plaintiff and the opinion of the District Court was by default. BS claims that *Blake* stands for the proposition that the OCSPA was abrogated by the OPLA. *Blake* actually stated that the OCSPA had "no application to this case because plaintiff's allegations are primarily rooted in product liability."

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However, *Blake* relied upon the Ohio Supreme Court case of *Carrell v. Allied Products Corp.*, 78 Ohio St. 3d 284 (1997), 677 M. E. 2nd 795, (1997). In *Carrell*, the Supreme Court ruled that only those common law claims specifically contained in the OPLA were actually abrogated so that a negligent design claim alleged in *Carrell* was not abrogated. Further, the OPLA does not contain any reference to the OCSPA. While *Carrell* was eventually addressed by the Ohio Legislature, the OCSPA was never abrogated by the OPLA. The OPLA only abrogated "product liability claims or causes of action." *Wright v. Harts Mach. Servs., Inc.*, 6th Dist., Fulton No. F-15-004, 2016-Ohio-4758, ¶ 28, 69 N.E.3d 63, ¶ 28 (June 30, 2016), citing R.C. § 2307.71(B).

Further, the Defendant's claim that when alleging a cause of action involving a statutory provision, the statutory provision must be specified in the allegation of the Complaint. This is not accurate. What Ohio Courts provide with regard to this proposition is as follows:

> Ohio is a notice pleading state. Pursuant to notice pleading, "'[appellant was] required to allege sufficient facts to give [appellees] notice of [his] claim.'" *Wiltz v. Accountancy Bd. of Ohio*, 10th Dist. No. 14AP-645, 2015-Ohio-2493, ¶ 13, quoting *San Allen, Inc. v. Buehrer*, 8th Dist. No. 99786, 2014-Ohio-2071, ¶ 84, referencing *Thatcher v. Lauffer Ravines, L.L.C.*, 10th Dist. No. 11AP-851, 2012-Ohio-6193, ¶ 43-48 ("Although claim was 'not spelled out in the complaint by explicit reference to the appropriate statutory sections,' " the case could nevertheless proceed on the theory that Defendant violated various statutory provisions if the allegations in the complaint " 'provided fair notice to the Defendants that the action could proceed on this theory.' "). "'Notice pleading under Civ. R. 8(A)(1) and (E) require that a claim concisely set forth only those operative facts sufficient to give "fair notice of the nature of the action."'" *Wiltz* at ¶ 13, quoting *Montgomery v. Ohio State Univ.*, 10th Dist. No. 11AP-1024, 2012-Ohio-5489, ¶ 20, quoting *Ford v. Brooks*, 10th Dist. No. 11AP-664, 2012-Ohio-943, ¶ 13.

Byrd v. Ohio Inspector Gen., 10th Dist. Franklin No. 21AP-578, 2022-Ohio-1827, 2022 WL 1744750, ¶ 14 (May 31, 2022).

Further, BS has not taken into consideration that a Plaintiff may allege alternative and/or even inconsistent claims.

pursuant to Civ. R. 8(E)(2):

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> A party may set forth two or more statements of a claim or defense alternately or hypothetically, either in one count or defense or in separate counts or defenses. * * * A party may also state as many separate claims or defenses as he has regardless of consistency and whether based on legal or equitable grounds.
>
> Thus, Civ. R. 8(E)(2) "permits alternative or hypothetical pleading, or even the use of inconsistent claims." *Iacono v. Anderson Concrete Corp.*, 42 Ohio St.2d 88, 92, 326 N.E.2d 267 (1975).
>
> Because alternative pleading is permissible, a party may plead both a breach-of-contract claim and an unjust-enrichment claim without negating the validity of either claim. *Bldg. Indus. Consultants, Inc. v. 3M Parkway, Inc.*, 182 Ohio App.3d 39, 2009-Ohio-1910, 911 N.E.2d 356, ¶ 17 (9th Dist.) ("While it is true that a party may not recover for the same services under both a contractual claim and a claim for [unjust enrichment], a party is not barred from seeking alternative theories and recovering under a[n] [unjust-enrichment] theory if his contractual claim fails."); *accord Advanced Travel Nurses, L.L.C. v. Watson*, 2d Dist. No. 24628, 2012-Ohio-3107, 2012 WL 2630431, ¶ 28; *Firelands Regional Med. Ctr. v. Jeavons*, 6th Dist. No. E-07-068, 2008-Ohio-5031, 2008 WL 4408600, ¶ 31. The mere presence of both claims in a complaint does not warrant the dismissal of the unjust-enrichment claim on a Civ. R. 12(B)(6) motion. *Perrysburg Twp. v. Rossford*, 149 Ohio App.3d 645, 2002-Ohio-5498, 778 N.E.2d 619, ¶ 52 (6th Dist.), *modified*, 2002-Ohio-6364, 2002 WL 31630765, *aff'd*, 103 Ohio St.3d 79, 2004-Ohio-4362, 814 N.E.2d 44. Thus, the trial court erred in dismissing Cristino's claim for unjust enrichment.

Cristino v. Bur. of Workers' Comp., 10th Dist. Franklin No. 12AP-60, 2012-Ohio-4420, ¶ 25-26, 977 N.E.2d 742 (Sept. 27, 2012).

In *Cristino,* Plaintiffs filed a cause of action against the Defendant for breach of contract, breach of fiduciary duty, fraud, unjust enrichment, and various violations of constitutional and statutory rights. The Franklin County Court of Common Pleas dismissed the Complaint upon the Defendant's Motion to Dismiss. Among other things, the court found that the dismissal of the fraud claim was not warranted and that the Plaintiffs' claim for breach of contract, did not prevent the Plaintiffs' from also pleading an inconsistent claim for unjust enrichment. The court specifically ruled that Civ. R. 8(E)(2) permits inconsistent pleadings. In the case sub judice, the Plaintiff is permitted to plead alternative and even inconsistent causes of action. Therefore, the Motion to Dismiss is at best, premature and after discovery, the Defendant can address these issues with a

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Motion for Summary Judgment and/or even a Motion in Limine.

II. RES IPSA LOQUITUR

BS states that Res Ipsa is not a cause of action. The Plaintiff agrees and the Plaintiff never alleged that it was. It is common knowledge that Res Ipsa is a rule of evidence, and it must be pled if a Defendant intends to assert it. The Ohio Supreme Court stated as follows:

> The Ohio Supreme Court has explained that the doctrine of Res Ipsa loquitur is an evidentiary rule that allows the factfinder "to draw an inference of negligence when the logical premises for the inference are demonstrated. * * * [i]t is merely a method of providing the Defendant's negligence through the use of circumstantial evidence." *Morgan v. Children's Hosp.,* 18 Ohio St.3d 185, 187, 480 N.E.2d 464 (1985), quoting *Jennings Buick Inc. v. Cincinnati,* 63 Ohio St.2d 167, 169-170, 406 N.E.2d 1385 (1980).

Drew-Mansfield v. MetroHealth Med. Ctr., 8 Dist. Cuyahoga No. 102254, 2015-Ohio-3033, 2015 WL 4599435, ¶4 (July 30, 2015).

If the Plaintiffs did not place BS on notice of their intent to utilize the doctrine, BS's Representative would be standing on the trial table protesting that they were not informed by Plaintiffs of their intent to assert Res Ipsa. The Defendant is apparently claiming that this evidentiary rule that has existed in Ohio, and every other state in the country, was somehow abrogated by the OPLA. This is not accurate. A jury can certainly take into consideration that the Plaintiff underwent a urological surgical procedure at the Cleveland Clinic over one year ago with control of his bladder and then lost complete control of his ability to urinate immediately following the procedure, the Plaintiff is confined to his home to this day because of the loss of this bodily organ system.

III. THE F.D.A. REGULATIONS AND THEIR USE IN TRIAL

The Defendants have claimed that the Plaintiffs are attempting to use the Food and Drug Administration ("F.D.A.") regulations as a cause of action. This is not accurate. The F.D.A.

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regulations may be used to form an evidentiary basis for a cause of action, i.e. failure to warn.

Multiple cases stand for the proposition that the F.D.A. regulations or for that matter, any regulations promulgated by a Regulatory Agency may be used to support a claim. Violation of F.D.A. regulations can form the underpinnings of causes of action under the Ohio Products Liability Act as follows:

> To be sure, Paragraphs 10 and 11 of the Complaint include factual allegations regarding Endo's contacts with the Food and Drug Administration ("F.D.A."), and particularly Endo's purported admissions to the F.D.A. in late 2012 that the non-crush resistant form of OPANA tablets (the same form that Powell allegedly ingested) was inherently dangerous, that Endo had developed a new crush resistant form of those tablets in late 2011 or early 2012, and that the F.D.A. should forbid generic drug manufacturers from making the non-crush resistant form. (Doc. 1, Exh. A, at 10 ¶¶ 10-11.) The point of these F.D.A. references in the Complaint was not that F.D.A. regulations provide the relevant standard of care or that Endo ever diverged from F.D.A. authorities or requirements; rather, the obvious utility of those factual allegations to Brown was that they tend to show Endo's awareness of the dangerous nature of non-crushable Opana and its development of a safer alternative form of the drug months before Powell died by crushing and ingesting Opana in a form that Endo knew to be unsafe. In short, these scant mentions of the F.D.A. in the Complaint are not indicative of the joinder of a federal issue in this action.

Brown v. Endo Pharm., Inc., 38 F. Supp. 3d 1312, 1318, fn. 3 (S.D. Ala. 2014).

The Plaintiff alleges that his surgeon utilized BS's Rezum Delivery System to treat the Plaintiff's bladder for BPH. In paragraphs 20 through 37 ("P-20-37"), the Plaintiffs sets forth in vigorous detail various mandates from the F.D.A. that control BS's Rezum medical device. These mandates include the requirement that BS report to the F.D.A. any adverse event that BS becomes aware of, within 30 days after the date they become aware of it (P-29). BS is required to conduct an investigation of each of those adverse events (P-30). BS is required to issue its reports of those investigations to the F.D.A. (P-31). BS is required to establish an internal procedure for reviewing those adverse events and to establish and maintain an adverse event "database" (P-32). The Plaintiffs' have every right to review that "database of adverse events" that the F.D.A.

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mandates.

The adverse event reports that are required to be chronicled by BS is referred to as the Manufacture and User or Facility Device Experience ("MAUDE"). There were over 300 adverse events reported to the F.D.A. regarding BS's Rezum Delivery System and chronicled in MAUDE, including multiple injuries and malfunctions of the Rezum Delivery System (P-29-37).

P-36 sets forth that the MAUDE adverse events were included as an attachment to the complaint, and they are going to be forwarded either by flash drive or by dropbox to the staff attorney for the trial court. (The Clerk could not include the MAUDE Report because it is an Excel spreadsheet).

The MAUDE reports are used in cases throughout the country as support for various claims just as it is being used as support for various claims in this case against BS. While it is understandable that BS would like to eliminate the plethora of inflammatory adverse incidents chronicled in the MAUDE report, these claims are appropriate as set forth in Plaintiffs' Complaint in detail.. As further support for this proposition:

> As Plaintiffs contend and as the Court has noted, Plaintiffs' off-label claims do not depend on a finding that AbbVie violated the FDCA or F.D.A. regulations. For example, a reasonable jury could find AbbVie liable for making misrepresentations about the safety and efficacy of AndroGel for treating age-related hypogonadism or for making misrepresentations about the indications for which the F.D.A. approved AndroGel. And although Plaintiffs' complaints make reference to regulations regarding misbranding, they do so in the context of establishing the standard of care that they contend AbbVie breached, and to help establish AbbVie's intent and motive in connection with its marketing of AndroGel. *See, e.g.,* Fourth Am. Master Compl. ¶¶4944-500. The fact that Plaintiffs cannot assert claims to enforce the FDCA's prohibitions or requirements does not preclude them from, for example, introducing evidence regarding the indications for which the F.D.A. approved AndroGel. *Buckman* does not mean Plaintiffs cannot bring state law claims based on conduct that violates the FDCA." *Edison v. Medtronic, Inc.* 981 F. Supp. 2d 868, 880-81 (N.D. Cal. 2013).

In re Testosterone Replacement Therapy Products Liab. Litig. Coordinated Pretrial Proceedings, N.D. Ill. No. 14 C 1748, 2017 WL 1836443, *8 (May 8, 2017).

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P-21 of the Complaint further sets forth that BS failed to require certifications of physicians utilizing Rezum to ensure that they were properly trained and to further ensure that physicians have a complete understanding of the application of treatments and potential consequences of mistreatment. (By way of example attached hereto as exhibit ("A") is the BS instruction pamphlet for Rezum. On the front page, listed under "warnings", is the following: "training: Boston Scientific requires physician training specific to the Rezum Delivery System procedure prior to use.") Since the court takes the allegations in the Complaint as true, BS failed to provide that training as stated and advertised. (P-21,22) R.C. §2307.76 and R.C. §2307.77. OPLA specifically provides that a product is defective due to inadequate warning or instructions, or a misrepresentation made by the manufacturer. These allegations in accordance with R.C. § 2307.77 and R.C. § 2307.76 are clearly pled in Plaintiffs' Complaint. The BS warning herein stated is not true. It is not just misleading, it is blatant fraud.

P-22, 23 and 24 of Plaintiffs' Complaint, states that BS is required to give "adequate" instructions for using the medical device such that "a layman can use a device safely and for the purpose for which it is intended", and further cites 21 CFR § 810.5 and 21 USC § 321, 352 and 331) pertaining to requirements governing the appearance of the label. This violates R.C. § 2307.76(A)(1), § 2307.76(A)(2) and § 2307.77, in that BS failed to provide adequate warning and/or instruction for using the Rezum Delivery System.

P-25 contains an F.D.A. regulation that requires medical device manufacturers to disclose all material facts in advertising and labeling and false or misleading labeling is considered misbranded, which is prohibited by 21 U.S.C. § 321, 352, and 331. This is also a violation of the OPLA. (See R.C. § 2307.76 and R.C. § 2307.77.) Specifically, BS failed to inform patients that physicians were not trained to use Rezum or that BS did not train the physicians using the product.

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P-28-34 sets forth that the failure to follow the labeling and promotional advertisements as they are deemed to be misleading, including failing to disclose product risks, particularly the risks from adverse events reported by physicians and consumers use of the BS Rezum product. (The Complaint further sets forth violations of the OPLA, in particular, R.C. § 2307.76 and R.C. § 2307.77 and failing to warn.)

NEGLIGENCE

P-35 alleges that a Representative of BS was present with the codefendant physician during the Plaintiff's urological surgical procedure wherein the surgeon utilized the Rezum Delivery System, and that the unknown Representative of BS negligently misguided the surgeon in the use of the Rezum product and negligently failed to intervene when it was appropriate to do so. This allegation is taken as true. It is outside of the OPLA and refers to an individual Representative of BS and the co-defendant physician whose negligence caused injury. Obviously, not all of the Plaintiffs' claims refer solely to BS, as BS has argued.

NEGLIGENCE PER SE

Plaintiffs' Complaint sets forth the dynamics of negligence per se in that BS's violations of F.D.A. regulations can be used in the negligence claims against the BS Representative and the (OPLA) statutory violations of BS (P-38, 39 and 40). The Plaintiffs contend that the violation of the regulations constitutes negligence per se. Negligence per se is not a cause of action and it has not been abrogated by OPLA as the Defendants argue. It is a concept for imposing liability on a Defendant. It can be used to substantiate and support the causes of action set forth herein against BS and potentially could be used in a jury instruction as an appendage to the multiple violations of the OPLA set forth herein. It can also be used to support the cause of action against the Representative of BS that was present during the surgical procedure.

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FAILURE OF THE REZUM DELIVERY SYSTEM TO CONFORM TO REPRESENTATIONS MADE BY BS

P 41-45, Count V, is an allegation that the Rezum Delivery System "did not conform to Boston Scientific's representations" that the device was safe. This language is directly from R.C. § 2307.77 (OPLA). Traditionally, these same allegations were also made in terms of breach of warranties and merchantability that are now merged into OPLA. In Plaintiffs allegations these causes of action are stated with specificity in the Complaint.

P-21 further alleges that Boston Scientific failed to require certifications of physicians utilizing the Rezum Delivery System, to ensure that those physicians operating this medical device are properly trained and had an understanding of the application of treatments and potential consequences of utilizing their medical device. The allegation herein is in specific reference to R.C. § 2307.76.

P-29 and P-30 states the F.D.A. provides that BS is required to chronicle, no later than 30 calendar days after any adverse event that BS becomes aware of and mandates that BS is responsible for conducting an investigation of each adverse event and must evaluate the cause. (21 CFR §803.50 (a). Depositions and common sense will be utilized to demonstrate BS was aware of defects in Rezum that caused injury and violate the OPLA, in particular R.C. 2307.76 and R.C. 2307.77)

P-31, 32, 33 and 34, mandates that BS is required to report all information regarding the adverse events, to make periodic reports regarding the adverse events, to continue to monitor the Rezum product after premarket approval, to "establish and maintain" an adverse event "database" describing the events and the remedial action taken. The Complaint alleges BS has not complied with these mandates associated with the Rezum product. (R.C. 2307.76(A).

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STRICT LIABILITY FOR MANUFACTURING DEFECT

P-58-63 sets forth violations of R.C. § 2307.76. The allegations, in terms of strict liability pursuant to the restatement of torts, that the Rezum Delivery System, without substantial change to its condition as manufactured by BS, contained defects that the Plaintiff was not aware of and was not warned of and could not have reasonably known about. Those defects and injuries caused and categorically chronicled in the MAUDE report were known to BS and BS failed to divulge the defectively caused risks to the public, including the Plaintiff. In further violation of OPLA, R.C. § 2307.76 the Plaintiff alleges the Rezum Delivery System caused increased risk of excess tissue loss and nerve damage and this information was not provided to Dr. Eltemamy whom the Plaintiffs contend had no certification of training on the Rezum Delivery System. Consequently, BS's conduct in failing to notify or warn the Plaintiff or his physician of those risks constitutes a violation of OPLA. The OPLA refers to this as "defective". This is specifically alleged in the Plaintiffs' Complaint.

VIOLATIONS OF OHIO CONSUMER PROTECTION STATUTE

What is referred to as Count IX, P-64-73 in the Plaintiffs' Complaint, the Plaintiff goes to great lengths to specify what statutory provisions of the OCSPA were violated by BS. As previously stated *supra,* OCSPA was not abrogated by the OPLA as BS claims. Even though Defendants incorrectly state it was abrogated with citations that do not stand for that proposition. Further, even if the OCSPA were abrogated by OPLA, the Plaintiff is permitted, pursuant to Civ. R. 8(E)(2), to plead in the alternative, or even to plead inconsistent allegations.

FAILURE TO WARN

P-78-81, in Count XI, specifically sets forth that BS was aware of hundreds of adverse events and failed to warn physicians and other members of the public, including the Plaintiff who

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would use the product, that the Rezum Delivery System created an unreasonably dangerous risk when utilized by physicians for use on patients. BS failed to take reasonable steps to give adequate warnings or instructions to others about the risks that were gleaned from the MAUDE chronicles to the public, including the Plaintiff, and that was a proximate cause of the Plaintiff's injury. (see Complaint) This specifically is in conformance with R.C. § 2307.76(A)(1) and (2) in that these allegations in Plaintiffs' Complaint are consistent with OPLA.

LIABILITY FOR DEFFECTIVE PRODUCT

BS complains at page 3 of their Motion to Dismiss that Plaintiff has not even pled "How the Rezum device was defective." Fortunately, the passage of the OPLA has made this task easier.

P-74-77, also referenced to as Count X, sets forth a cause of action for BS liability based on a manufacturing defect. Plaintiffs' Complaint sets forth a defect pursuant to R. C. § 2307.76(A)(1) because BS provided inadequate warning that was associated with the Rezum Delivery System when it was aware that over 300 injuries, malfunctions and even deaths occurred from the use of their product. The Complaint further states that the product was defective pursuant to R. C. § 2307.76(A)(2) because they didn't provide post marketing warnings or instructions, as BS was aware that physicians utilizing the Rezum product were not properly trained as BS claimed they were. BS also had knowledge of the risks that were associated with the product because of the F.D.A.'s publication of the adverse risks associated with Rezum. OPLA refers to these inadequate warnings as a defective product.

LOSS OF CONSORTIUM

Since the Plaintiffs claims against the Defendant are derivative of Veseljko Stojanovic's claim, his wife has a loss of consortium claim. The loss of consortium claim, was not abrogated by OPLA as the Defendants suggest.

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EMOTIONAL DISTRESS

The Defendant even goes so far as to claim that an emotional distress claim in the Plaintiffs' Complaint is a "cause of action". The Plaintiffs' claim of emotional distress is primarily a damages claim. It was not abrogated by the OPLA.

CONCLUSION

Plaintiffs moves the trial court to deny BS's Motion to Dismiss so BS can file an Answer and let discovery commence.

Respectfully Submitted,

/s/ William A. Carlin
WILLIAM A. CARLIN 0009144
29325 Chagrin Blvd., Ste. 305
Pepper Pike, Ohio 44122
TEL: 216/831-4935
FAX: 216/831-9526
WcarlinEsq@aol.com

CERTIFICATE OF SERVICE

I hereby certify that, on July 31, 2022, a copy of this Motion was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's system.

/s/ William A. Carlin
William A. Carlin (0009144)

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Boston Scientific

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rezūm™
Delivery Device Kit for BPH

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

SAFETY

This section contains important safety information. Boston Scientific requires that you read and understand all warnings, cautions, precautions and the operator's manual prior to using the Rezūm System.

WARNINGS

Training: Boston Scientific requires physician training specific to the Rezūm System procedure prior to use. Please contact Boston Scientific for more information.

Familiarity with Cystoscopic Procedures: Users should be familiar with cystoscopic procedures and techniques for treating benign prostatic hyperplasia before using the Rezūm System.

Use Under Prescription: Federal Law restricts this device to sale and use by or on the order of a physician (or properly licensed practitioner).

Tissue Healing After Biopsy or Prior Prostate Surgery: After biopsy or prior prostate surgery, allow tissue to heal (e.g. 30 days) prior to performing Rezūm System procedure.

Priming Cycle: Point the Delivery Device tip away from patient or personnel during the priming cycle. Vapor coming out of the tip is hot and can burn the skin.

Flush Button Pressure: Excessive pressure while using Flush Activation Button may cause unintended deployment of the needle.

Needle Placement: Proper placement of the needle is essential. Do not direct the needle downward toward the rectum.

Location of Verumontanum: Prior to each treatment, know where the verumontanum is in relation to the tip of the shaft. All treatments should be placed proximal to the verumontanum.

Needle Tip: Do not start treatment if the black depth marker on the needle is still visible after needle deployment. If the marker is still visible, push the needle deeper into the prostate until no black is visible through the lens. If unable to position correctly, deliver vapor for ~4 seconds to devascularize the site, then retract needle by pressing upward on the Needle Retraction Button. Reposition Delivery Device approximately 1 cm from the partially treated site and repeat needle deployment steps.

Needle Retraction: Prior to starting procedure, the needle should be fully retracted. During procedure, ensure needle is fully retracted by viewing needle position through scope lens. If needle is not retracted prior to repositioning Delivery Device, damage to urethra may occur.

Sterility/Damaged Packaging: Do not use the Delivery Device and its contents if the packaging's sterile barrier is broken, the seal is damaged, or the device is damaged.

Manual Needle Retraction: Do not remove device from the patient if the needle is not fully retracted. In case of incomplete needle retraction, manually retract the needle before removing the device from the patient. For instructions on how to manually retract the needle, see Method for Manual Needle Retraction section. Do not attempt to reassemble device for reuse after manual needle retraction.

Service or Maintenance While in Use in Patient: No modification of this equipment is allowed. Do not attempt to service or maintain the Generator while in use with a patient.

Urethral Strictures: Urethral strictures should be ruled out as a cause of obstruction prior to treatment with Rezūm.

PRECAUTIONS

Prior Radiation: There is no data on the use of this treatment in patients who have undergone prior radiation therapy in the pelvic region.

Single-Use Only Device: The Delivery Device is intended for single-use only. Do not reuse, reprocess or resterilize the device. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.

Exterior Surface of Sterile Water Vial: The exterior of the Sterile Water Vial is not sterile and should not be placed in the sterile field.

Positioning Saline Flush Line in Saline Pump: Reference indicators on Generator to ensure Saline Flush Line is positioned in the correct direction. If Saline Flush Line is placed in a backwards direction within the Saline Pump, saline will not flow during procedure.

Remaining Saline Level in Bag: Care should be taken during procedure to monitor remaining saline level in bag. If saline bag is empty, patient could experience urethral discomfort due to no flush flow.

Movement of Delivery Device: Once needle is deployed, hold the Delivery Device steady. Movement of the Delivery Device may stretch tissue and cause vapor to leak into the urethra, possibly causing urethral irritation. Extreme movement may also cause pressure on the needle resulting in difficulty with needle retraction. Needle must be returned to the original insertion position to facilitate retraction.

Overfilling of Bladder: Care should be taken during procedure to monitor the amount of saline instilled. If bladder is not empty, overfilling of bladder may occur. The Generator helps monitor the amount of saline instilled.

Continued or Worsening of LUTS: During healing phase, patient may experience a continued or worsening of LUTS, which may require the use of a catheter for several days. Cystoscopic intervention during the healing phase may also lead to continued or worsening of LUTS. For more information on these types of events in the clinical study, please refer to the Clinical Summary section of the DFU.

Room Temperature Saline: Saline should be at room temperature. Do not use cold saline, which may reduce the effectiveness of the therapy.

Scope Lens: The Delivery Device is compatible with a 4 mm, 30 degree, 30 cm Storz®, InnoView® or Richard-Wolf® cystoscopic lens. Use of other scope lenses may impact performance of the Delivery Device.

Priming Cycle: If finger is released from Vapor Activation Button before the priming cycle is complete, vapor will automatically stop and the priming steps will have to be repeated.

Vapor Activation: Do not release Vapor Activation button during vapor treatment cycle. If Vapor Activation Button is released before treatment cycle is complete, vapor release will automatically stop, which may lead to partial and incomplete treatment.

Air Bubbles in Syringe: Ensure air bubbles are removed from the syringe. If bubbles are trapped in the line, an insufficient treatment may result.

Excessive Treatments: Treatments in excess of those recommended in the guidelines may lead to prolonged irritative symptoms and/or catheterization.

Disposal Instructions: After use, this product should be treated as a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal guidelines.

INDICATIONS FOR USE

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia (BPH). It is indicated for men ≥ 50 years of age with a prostate volume 30 cm^3 ≤ 80 cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

CONTRAINDICATIONS

The use of the Rezūm System is contraindicated for the following:

- Patients with a urinary sphincter implant
- Patients who have a penile prosthesis
- Patients who have an active urinary tract infection

THE REZŪM SYSTEM OVERVIEW

The Rezūm System is designed to treat patients with bothersome urinary symptoms associated with BPH. The Rezūm System utilizes radiofrequency current to generate "wet" thermal energy in the form of water vapor, which is then injected into the transition zone and/or median lobe of the prostate tissue in controlled 9-second doses. The vapor that is injected into the prostate tissue rapidly disperses through the interstitial space between the tissue cells. As the vapor cools, it condenses immediately on contact with tissue and the stored thermal energy is released, denaturing the cell membranes and causing cell death.

The denatured cells are absorbed by the body, which reduces the volume of prostate tissue adjacent to the urethra. The vapor condensation process also causes a rapid collapse of vasculature in the treatment zone, resulting in a bloodless procedure.

Following thermal therapy for BPH, small pieces of coagulated tissue may slough off and be expelled via urination. This sloughing process may continue for a few months post-procedure, depending on the rate of healing.

CONTENTS

The Rezum System consists of the following:

- Rezūm Generator (reusable)
- Rezūm Delivery Device Kit (disposable)

REZŪM GENERATOR

The portable Rezūm Generator is provided with the following reusable components (Figure 1):

- Generator
- One Power Cord

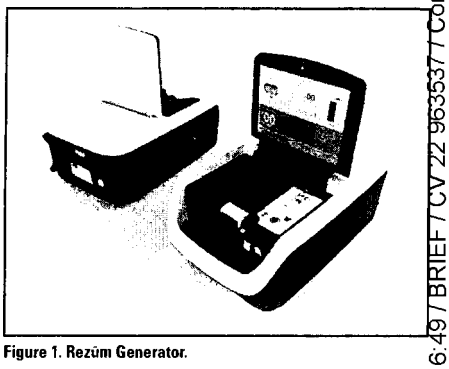

Figure 1. Rezūm Generator.

REZŪM DELIVERY DEVICE KIT

The Rezūm Delivery Device Kit contains the following disposable components:

- One sterile Delivery Device with cable and tubing
- One sterile Syringe
- One sterile Spike Adaptor
- One Sterile Water Vial

Rezūm Delivery Device Component Functions and Specifications (Table 1).

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EXHIBIT A

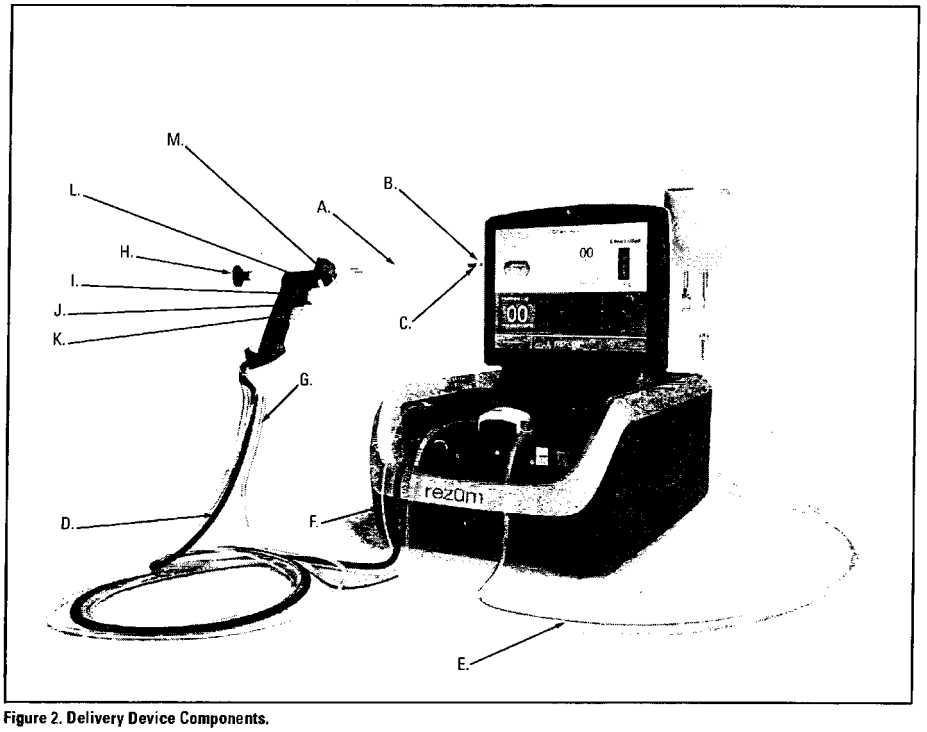

Figure 2. Delivery Device Components.

Table 1. Functional Description of the Delivery Device

Description	Function
A. Shaft	Provides enclosed channel for needle, vapor tubing, rigid scope lens and flush irrigation.
B. Tip	Guides shaft into treatment area and houses needle.
C. Needle	Inserted into the targeted prostate tissue to deliver vapor treatment.
D. RF Cable	The RF cable is the energy line and connections for the switches and thermocouples.
E. Saline Flush Line	Provides saline flush for irrigation through the Delivery Device.
F. Water Line	Line to move water into the Delivery Device.
G. Drain Line	Line to allow urine to be drained from the bladder.
H. Rigid Cystoscope Lens Port	Provides secure connection of rigid cystoscope lens in Delivery Device.
I. Flush Activation Button	Provides saline flush (normal, high). Top, front button (white).
J. Needle Deployment Button	Located behind the flush button, deploys the needle into the prostate tissue. Top, back button (grey).
K. Vapor Activation Button	Activates vapor after needle has been deployed. Bottom button (blue).
L. Needle Retraction Button	Retracts needle back into Delivery Device shaft. Grey button located on the underside of the nose cone.
M. Nose Cone Release Pin	Detaches shaft from Delivery Device to allow the safe manual retraction of needle into shaft if Needle Retraction Button fails.

THE REZūM PROCEDURE

User Supplied Materials

Other materials that are typically required for the Rezūm™ System procedure include, but are not limited to, the following items.

- Cart or sturdy surface for the Rezūm Generator
- Prep tray
- Topical antiseptic (e.g. Betadine)
- Patient drape
- Disposable underpads (e.g. Chux)
- Gauze squares
- Lidocaine gel anesthetic or water-soluble lubricating gel
- Saline supply at room temperature (1 L, 2 L, 3 L, 4 L, 5 L or 500 ml)
- IV pole for Saline supply
- 4 mm, 30 degree, 30 cm Storz®, InnoView® or Richard-Wolf® rigid cystoscope lens
- Light source and cord
- Video camera and display; recorder optional
- Drain bucket
- Hemostat

Preparing the Patient

1. Prior to the procedure, administer physician-preferred pain and/or anti-anxiety medication. If using oral medications, allow sufficient time for the medications to reach peak levels.
2. Instruct patient to completely void bladder prior to procedure.

Caution: Care should be taken during procedure to monitor the amount of saline instilled. If bladder is not empty, overfilling of bladder may occur. The Generator helps monitor the amount of saline instilled.

3. Ten minutes prior to the procedure, prepare and drape the patient using standard cystoscopy guidelines.
4. Place the patient in the lithotomy position. Ensure buttocks are resting at the edge of the table to both enable entry deep enough into the anatomy and also to allow for easier Delivery Device rotation during the procedure.

Power Up the Rezūm Generator

1. Generator should be placed within reach of patient and an electrical outlet to supply power to the unit.
2. Place prep tray or cart near the Generator.
3. Open the display screen.
4. Plug the power cord from the Generator into an electrical outlet (Figure 3).

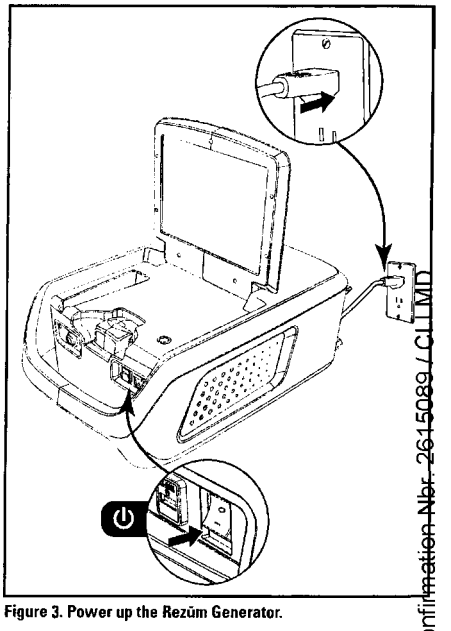

Figure 3. Power up the Rezūm Generator.

5. Turn on the Generator.
6. The Generator is in an inactive state until a valid Delivery Device is connected.

Prepare the Sterile Saline Bag

1. Obtain a brand new bag of saline fluid. 500 mL, 1000 mL, 2000 mL, 3000 mL, 4000 mL and 5000 mL volume options are compatible with the Rezūm Generator.
2. Hang bag on an IV pole (Figure 4).

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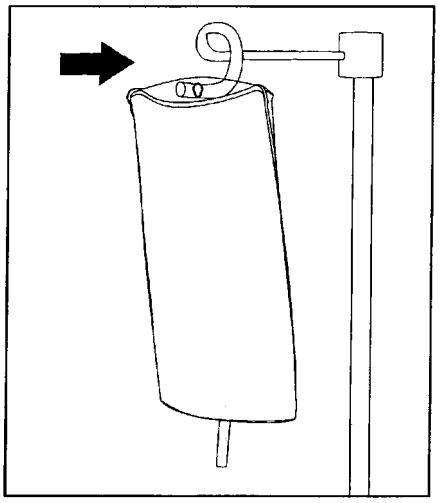

Figure 4. Hang the saline bag on IV pole.

Note: Bag spike is NOT needed; spike is pre-attached to Delivery Device Saline Line Tubing.

Caution: Saline should be at room temperature. Do not use cold saline, as it may reduce the effectiveness of the therapy.

Unpack Contents of Delivery Device Kit

Warning: Do not use the Delivery Device and its contents if the packaging's sterile barrier is broken, the seal is damaged, or the device is damaged.

Caution: The exterior of the Sterile Water Vial is not sterile and should not be placed in the sterile field.

1. Prior to opening, inspect the integrity of the outside and inside packaging to ensure sterility. Do not use if the packaging is damaged.
2. Lay out sterile field and place lubricating gel in sterile field.
3. Remove the Sterile Water Vial from the corner of the box. Remove the cover from the water vial and wipe with a sterile wipe. Place bottle outside of the sterile field.
4. Using sterile technique, remove the Tyvek® cover from the tray and remove and discard retainer tray.

Prepare the Syringe

1. Using appropriate aseptic practices, remove Syringe and Spike adaptor.
2. Connect Spike adaptor to Syringe. Ensure connection ends remain sterile.
3. Remove protective cover from Spike and insert Spike into Sterile Water Vial.
4. Invert Sterile Water Vial and slowly pull back plunger shaft to fill Syringe (Figure 5). Remove plunger shaft once Syringe is filled.

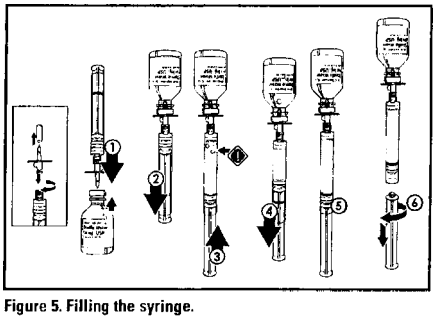

Figure 5. Filling the syringe.

Caution: Ensure air bubbles are removed from the syringe. If bubbles are trapped in the line, an insufficient treatment may result.

5. Keeping the Syringe connected to the Spike Adaptor and Sterile Water Vial, set aside outside the sterile field.

Set Up the Rezūm™ Delivery Device

1. Remove the Delivery Device RF cable and plug into generator, ensuring white dot on the top of the plug is aligned with red dot on the generator port (Figure 6).

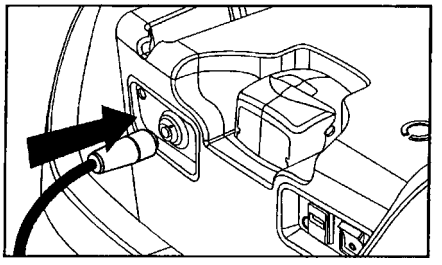

Figure 6. Connecting cable into Generator.

2. Ensure needle has retracted on Delivery Device.
3. Remove Saline Flush Line and Water Line from tray.
4. Place the Saline Flush Line in the Saline Pump. Ensure Saline Flush Line is seated such that the Saline Pump door can close smoothly. Align the color indicators on the generator and saline flush line (Figure 7).

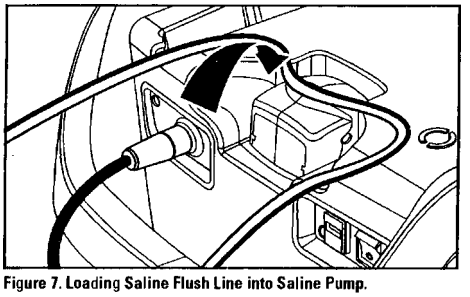

Figure 7. Loading Saline Flush Line into Saline Pump.

Caution: Use indicators on Generator to ensure Saline Flush Line is positioned in the correct direction. If Saline Flush Line is placed in a backwards direction within the Saline Pump, saline will not flow during procedure.

5. Close Saline Pump door prior to attaching Saline Flush Line tip to the Saline bag.

Note: If Saline Flush Line tip is attached to Saline bag prior to placing Saline Flush Line in the Saline Pump and closing the Saline Pump door, saline may leak.

6. Remove cap from tip of Saline Flush Line and attach to the saline source (Figure 8). Ensure clamp on Saline Flush Line is open.

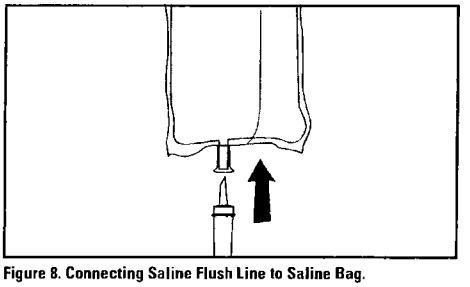

Figure 8. Connecting Saline Flush Line to Saline Bag.

7. Remove Spike Adaptor and Sterile Water Vial from Syringe.
8. Load the filled Syringe into the Syringe cradle (Figure 9).

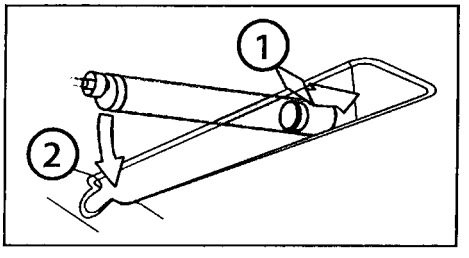

Figure 9. Loading Syringe.

Note: Syringe luer should be positioned on top of the Syringe to push fluid out of the Syringe.

9. Remove cap from Water Line luer and connect Syringe to Water Line by twisting the luer on the prefilled Syringe. Pressure relief valve on Water Line should be pointing down.
10. Using sterile technique, close clamp on Drain Line to ensure saline flows through Delivery Device during the procedure (Figure 10).

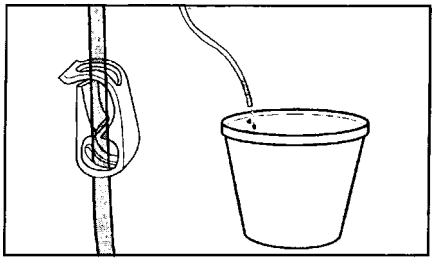

Figure 10. Closing clamp on Drain Line.

11. Using sterile technique, remove Delivery Device from packaging tray.

Insert the Rigid Cystoscope Lens

The Delivery Device is compatible with a 4 mm, 30 degree, 30 cm length Storz®, InnoView® or Richard-Wolf® rigid cystoscope lens. The lens provides direct or video display visualization to help the physician position the Delivery Device needle within the prostatic urethra.

Caution: The Delivery Device is compatible with a 4 mm, 30 degree, 30 cm Storz, InnoView or Richard-Wolf cystoscopic lens.
Use of other scope lenses may impact performance of the Delivery Device.

1. Inspect and ensure lens is cleaned and prepared per manufacturer's instructions prior to use.
2. Coat lens shaft near lens tip with lidocaine gel anesthetic or water soluble lubrication to ensure smooth insertion into Delivery Device. Do not coat the lens itself, as this may impede visualization (Figure 11).

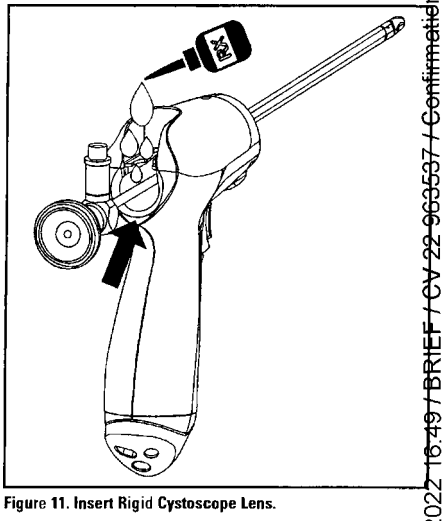

Figure 11. Insert Rigid Cystoscope Lens.

3. Gently insert the lens into the lens port and advance into position until it snaps into place.

Priming the Delivery Device

Warning: Point the Delivery Device tip away from patient or personnel during the priming cycle. Vapor coming out of the tip is hot and can burn the skin.

1. Prime the Delivery Device using the following steps (Figure 12):

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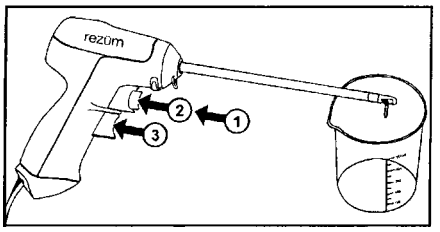

Figure 12. Steps for Activating Vapor Treatment.

A. Hold tip of Delivery Device over a liquid waste container.

Note: Ensure tip remains sterile.

B. Pull in Flush Activation Button (1) and Needle Deployment Button (2) until needle is deployed. Release both buttons once needle is deployed.

C. Pull in Vapor Activation Button (3) and hold to activate the vapor until the display screen indicates the priming cycle is complete (approximately 30 seconds).

D. Toward the end of the priming cycle, visually verify vapor is coming out of the needle tip.

E. When priming cycle is complete, release the Vapor Activation Button and retract the Needle by pushing upward on the Needle Retraction Button.

Caution: If finger is released from Vapor Activation Button before the priming cycle is complete, vapor will automatically stop, and the priming steps will have to be repeated.

F. If the Vapor Activation Button is released before the end of the priming cycle, repeat the priming cycle (steps A to E).

G. If priming cycle is not successfully completed, repeat steps a to e or replace Delivery Device.

Perform the Pre-Treatment Vapor Cycle

1. Activate idle feature by running a pre-treatment vapor cycle. Idle feature heats coil to keep water in a ready state so vapor delivery is immediate. If this step is not completed, condensation may build up between treatments, which may lead to insufficient treatment.
2. Pull in Flush Activation Button (1) Needle Deployment Button (2) and then Vapor Activation (3) (Figure 12).
3. During pre-treatment vapor cycle, observe flush exiting tip.
4. When pre-treatment vapor cycle is complete, release the Vapor Activation Button and retract the needle by pushing upward on the Needle Retraction Button.

Note: Pre-treatment vapor cycle must be completed prior to inserting Delivery Device into the patient.

Perform the Rezūm™ Vapor Treatment

1. Confirm the Generator display is showing the Therapy Screen.
2. Coat the shaft of the Delivery Device with water-soluble lubricating or anesthetizing gel.
3. Attach light cord and video camera to the scope lens.
4. Using finger, activate the saline flush by applying gentle pressure to the Flush Activation Button.
5. Carefully insert the Delivery Device into the urethra through the meatus.

Warning: Excessive pressure while using Flush Activation Button may cause unintended deployment of the needle.

Warning: Ensure needle is fully retracted by viewing needle position through scope lens. If needle is not retracted prior to insertion of the Delivery Device, damage to urethra may occur.

Warning: No modification of this equipment is allowed. Do not attempt to service or maintain the generator while in use with a patient.

6. While examining prostatic urethra, locate the apex of the prostate and the bladder. A TRUS and/or cystoscopy prior to the procedure can help obtain prostate measurements to determine the appropriate number of treatments.
7. Estimate the prostatic treatment length (i.e. from bladder neck to verumontanum). This length is considered the vapor treatment zone (Figure 13).

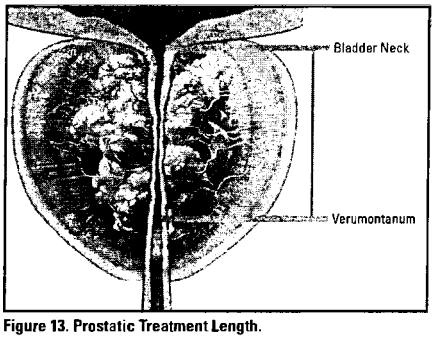

Figure 13. Prostatic Treatment Length.

8. Based on the length of the vapor treatment zone, determine the number of treatments per lobe (Table 2). A treatment consists of a single 9-second delivery of vapor.

Table 2. Guidelines for determining the number of treatments (lateral lobe).

Distance from Bladder Neck to Veru	Estimated Number of Treatments per Lobe
< 2.0 cm	1-2
2.0 – 3.0 cm	2-3
> 3.0 cm	3-4

9. If a median lobe is present and judged to be in need of treatment, deliver one treatment if median lobe is < 2 cm and two or more treatments if median lobe is > 2 cm. If central zone hyperplasia contributes to an elevated bladder neck with a prostatic urethral ≥ 35 degrees, as evidenced by sagittal TRUS, deliver one treatment for an enlarged central zone < 2 cm and two treatments for an enlarged central zone > 2 cm.

Caution: Treatments in excess of those recommended in the guidelines may lead to prolonged irritative symptoms and/or catheterization.

Note: A maximum number of 15 full treatments can be delivered with each Delivery Device.

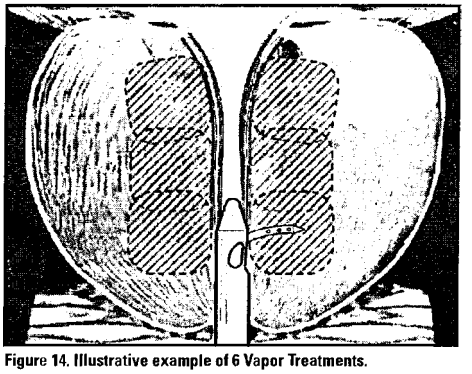

Figure 14. Illustrative example of 6 Vapor Treatments.

Warning: Proper placement of the needle is essential. Do not direct the needle downward toward the rectum.

10. Start the procedure by positioning the tip of the device just inside the bladder. Rotate the Delivery Device 90 degrees (horizontal) and bring device shaft just off floor of urethra.
11. While maintaining the 90 degree rotation, pull Delivery Device back into the urethra and position 1 cm back from the bladder neck. If treatment occurs within 1 cm of the bladder neck, short-term irritative symptoms may be experienced by the patient. Place the distal tip of the Delivery Device shaft against the lateral urethral wall.

Note: Optimal placement for the vapor treatment is in the crest of the lateral lobe. Ensure the shaft of the device is not close to the anterior surface, as this may lead to a sub-optimal treatment.

Note: On occasion, patient prostatic anatomy may restrict the Delivery Device tip from reaching the bladder neck. This may be due to an elevated bladder neck from central zone hyperplasia or a median lobe. On these occasions, do not force the device through tissue. Ensure the Delivery Device tip is proximal to the verumontanum and treat the bulk of the lateral lobe proximal to the verumontanum. Advance the Delivery Device in 1 cm increments toward the bladder neck to deliver subsequent vapor treatments. This may relax the tissue to allow the Delivery Device to reach the bladder neck. If the Delivery Device still cannot reach the bladder neck, treat the area that is proximal to the verumontanum.

12. Stabilize the Delivery Device before deploying the needle and remain completely still throughout the treatment.
13. While holding the Flush Activation Button, continue to pull in the Needle Deployment Button until the needle is deployed.
14. Visually verify the needle is fully inserted into the prostate by inspecting to see that the black depth marker just proximal to the emitter holes is not visible (no black should be seen).

Warning: Do not start treatment if the black depth marker on the needle is still visible after needle deployment. If the marker is still visible, push the needle deeper into the prostate until no black is visible through the lens. If unable to position correctly, deliver vapor for ~4 seconds to devascularize the site, then retract needle by pressing upward on the Needle retraction Button. Reposition Delivery Device approximately 1 cm from the partially treated site and repeat needle deployment steps.

15. Using finger, pull in Vapor Activation Button and hold to activate the vapor until treatment cycle is complete.

Caution: Once needle is deployed, hold the Delivery Device steady. Movement of the Delivery Device may stretch tissue and cause vapor to leak into the urethra, causing urethral irritation. Extreme movement may also cause pressure on the needle resulting in difficulty with needle retraction. Needle must be returned to the original insertion position to facilitate retraction.

Note: When the vapor treatment begins, the Rezūm System automatically tracks the time until the programmed treatment is complete and then automatically shuts off the vapor. Vapor can be stopped prior to treatment completion if Vapor Activation Button is released.

Caution: Do not release Vapor Activation Button during vapor treatment cycle. If Vapor Activation Button is released before the cycle is complete, vapor release will automatically stop, which may lead to partial and incomplete treatment.

16. The display screen will show each individual treatment time and count the number of full treatments that were completed.
17. Release Vapor Activation button and push upward on the Needle Retraction Button to retract the needle.

Warning: Ensure needle is fully retracted by viewing needle position through scope lens. If needle is not retracted prior to repositioning Delivery Device, damage to urethra may occur.

18. Reposition the Delivery Device for the next treatment by moving the device tip approximately 1 cm distal to the previous needle placement. The objective is to create contiguous, overlapping lesions, 1 cm apart, and running parallel to the prostatic urethra.
19. Maintain device rotation at 90 degrees between treatments to avoid losing sight of previous treatment location.
20. Follow the natural slope of the urethra to avoid being too close to the ceiling, i.e. too anterior. Center the needle between the floor and ceiling of the urethra and target the bulk of the adenoma directly if it is not centered.

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21. Complete steps 10-20 until all treatments in the first lateral lobe are complete. The final treatment location within each lobe should be on the proximal side of the verumontanum.

Warning: Prior to each treatment, know where the verumontanum is in relation to the tip of the shaft. All treatments should be placed proximal to the verumontanum.

22. Return Delivery Device to the start position at the bladder neck for treatments in the contralateral lobe. Rotate the Delivery Device 90 degrees to enable needle insertion at desired location on opposite lobe.
23. Repeat steps 10 through 20 until second lobe is fully treated.
24. For intravesical prostatic protrusions of either the lateral or median lobes, position Delivery Device 1 cm from the proximal edge of the protrusion and deliver the vapor treatment with the needle positioned approximately 45 degrees toward the midline. One treatment for a small median lobe (< 2 cm) and two or more treatments for a larger median lobe (> 2 cm). For an enlarged central zone, deliver treatments 1 cm from the bladder neck with the needle positioned at 45 degrees toward the midline of the tissue. Do not treat on the floor of the urethra within at least 1 cm of the verumontanum.

Caution: Care should be taken during procedure to monitor remaining saline level. If saline source is empty, patient could experience urethral discomfort due to no flush flow.

25. With lens in place, visually inspect the urethra and bladder at the end of the treatment and withdraw the Delivery Device from the urethra.
26. To conclude procedure, select Remove Device on Generator screen and follow instructions.

Post Procedure

1. Remove the Delivery Device from the urethra.
2. Remove the cystoscopic lens for cleaning and reprocessing.
3. Transfer procedure summary information to a portable USB memory device (Optional).
4. Disconnect the Delivery Device electrical cable from the Generator.
5. Open roller pump door and remove Saline Flush Line from pump.
6. Remove Syringe and Water Line from syringe cradle.
7. Dispose of Delivery Device and Syringe.

Caution: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal guidelines.

8. Turn the Generator off.
9. Disconnect the Generator from the electrical outlet.

METHOD FOR DRAINING THE BLADDER

If necessary during treatment, the bladder can be drained through the Delivery Device.

1. Ensure needle is retracted.
2. Place the tip of the Delivery Device in the bladder to drain.
3. Unclamp the drain line.
4. Remove scope lens to expedite draining of the bladder.
5. Select Drain Bladder on Generator to reset Saline Instilled.
6. When finished draining the bladder, reclamp the drain line.

METHOD FOR CLEARING VISUAL FIELD AND/OR REMOVING A CLOT

1. To clear bubbles from the field of vision and/or to remove a clot, activate the Turbo Flush feature by double tapping and holding the Flush Activation Button.
2. When visualization is cleared, release Flush Activation Button. Flush will run at normal rate the next time the Flush Activation Button is engaged.

METHOD FOR MANUAL NEEDLE RETRACTION

In the event the Needle Retraction Button fails to retract the needle fully into the Delivery Device shaft, follow the steps below to manually retract the needle into the Delivery Device shaft before removing the Delivery Device from the urethra. This should not occur under normal use and is designed only as a backup in case of device malfunction.

1. Disconnect Delivery Device Electrical Cable from the Generator.
2. Using a hemostat or other device, pull down and remove the release pin located below the nose cone to disengage the shaft assembly from the Delivery Device handle (Figure 15).

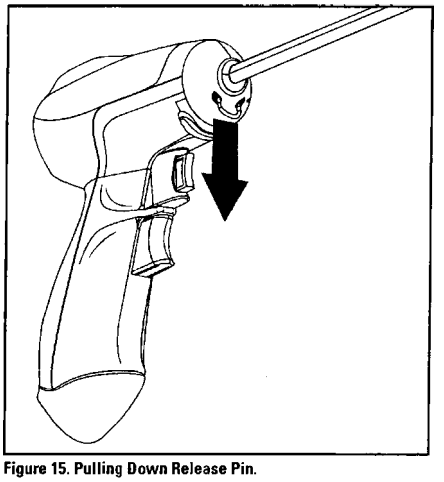

Figure 15. Pulling Down Release Pin.

3. Hold the shaft firmly in position and withdraw the handle just sufficiently to draw the needle into the shaft tip (1 inch minimum) (Figure 16).

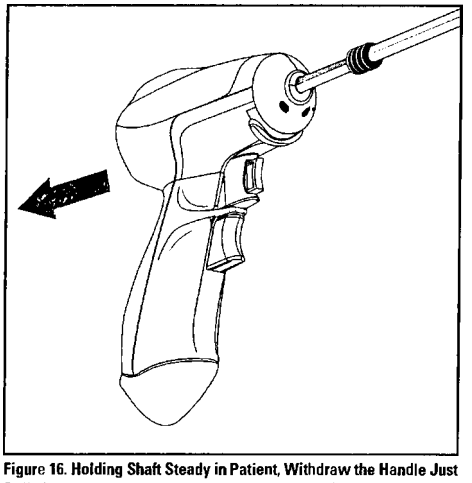

Figure 16. Holding Shaft Steady in Patient, Withdraw the Handle Just Sufficiently to Draw the Needle into the Shaft Tip (1 inch minimum).

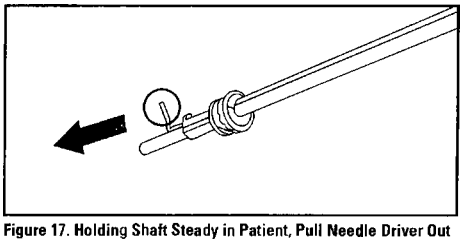

Figure 17. Holding Shaft Steady in Patient, Pull Needle Driver Out of Shaft to Retract Needle Into Tip.

Note: As the handle is being withdrawn, if the distal end of the needle body (in the handle) detaches from the handle and the proximal end of the needle is not drawn into the shaft tip, pull on the beige, right-angled plastic tube protruding from the shaft to manually retract the proximal end of the needle into the shaft tip (Fig. 17).

4. While maintaining the needle tip within the shaft, remove Delivery Device from patient.
5. If treatment is incomplete, re-start procedure with new Delivery Device and complete procedure.
6. Report all incidences of manual needle retraction to Boston Scientific Customer Service. Clean device and return to Boston Scientific.

Warning: Do not remove device from the patient if the needle is not fully retracted. In case of incomplete needle retraction, manually retract needle before removing the device from the patient. Do not attempt to reassemble device for reuse after manual needle retraction.

STORAGE, HANDLING, AND DISPOSAL

Rigid Cystoscope Lens

Refer to the rigid cystoscope lens packaging insert instructions for use for care, cleaning and handling.

Rezūm™ Delivery Device

The Delivery Device is shipped sterile. If the package sterile barrier is broken or missing, do not use the product.

The Delivery Device must not be reused or re-sterilized. It is for single use only.

The Delivery Device is packaged for easy transfer to the sterile field. The Delivery Device should be handled with care at all times. The storage area should have good ventilation, store in a cool, dry, dark place.

After use, discard the Delivery Device in accordance with local environmental regulations for biohazards material.

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Caution: The Delivery Device is intended for single-use only. Do not reuse, reprocess or resterilize the device. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.

Rezūm Generator

1. Unplug the power cord and store the cord with the Generator.
2. Clean the Generator as per the instructions found in the Rezūm Operator's Manual.
3. Close the display screen to protect it from damage.
4. Store the Rezūm Generator in a safe, clean and dry location.
5. To transport the Rezūm Generator, use handle to carry.

Disposal of the Product, Accessories and Packing Materials

Dispose of all products, accessories and packaging materials in accordance with hospital, administrative and/or local government policy.

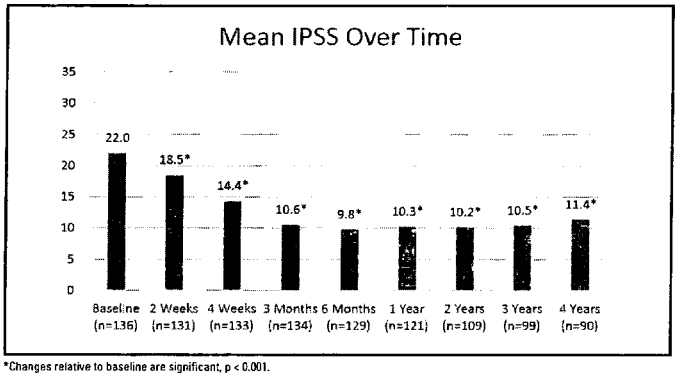
PIVOTAL CLINICAL STUDY SUMMARY

Efficacy

The Rezūm II Study was a multicenter, randomized, controlled, double-blinded study comparing the improvement in BPH symptoms at baseline and at 3 months post-procedure, as measured by IPSS, for subjects in the Treatment Arm as compared to subjects in the Control Arm. The Treatment Arm consisted of subjects receiving injections of water vapor into targeted zones of the prostate. The Control Arm consisted of subjects receiving a rigid cystoscopy with simulated active treatment sounds. The Treatment Arm demonstrated clinically, and statistically, significant mean improvement as compared to the Control Arm. The difference between the two arms was highly significant and the pre-specified, 3-month primary endpoint was met ($p < 0.0001$).

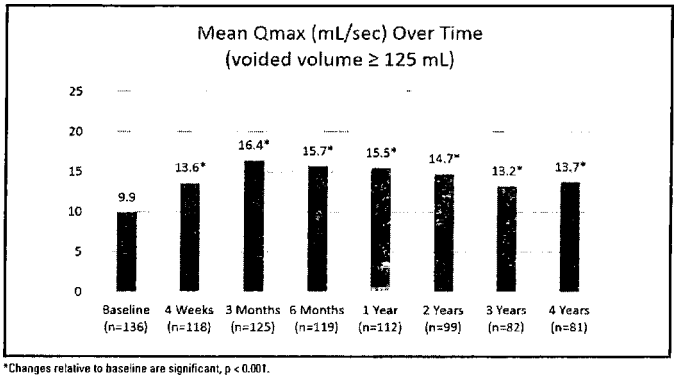
The graphs below summarize the Treatment Arm outcomes through 4 years for IPSS, Qmax, and Quality of Life.

Graph 1. Mean IPSS Over Time.



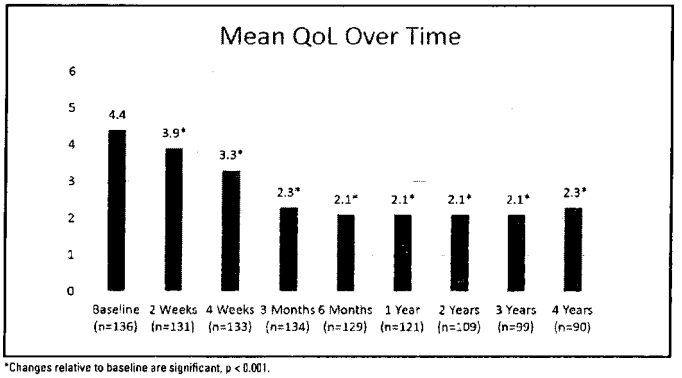
*Changes relative to baseline are significant, $p < 0.001$.

Graph 2. Mean Qmax Over Time.



*Changes relative to baseline are significant, $p < 0.001$.

Graph 3. Mean QoL Over Time.



*Changes relative to baseline are significant, $p < 0.001$.

REPORTED ADVERSE EVENTS

A summary of the adverse events reported and adjudicated in the Rezūm™ II Pivotal study at treatment out through report date of February 9, 2019 is presented in the table below. After unblinding at 3 months, the primary study endpoint, control subjects who elected to proceed were requalified by inclusion criteria and eligible to participate in a crossover study to receive thermal therapy. There were no unanticipated adverse device effects or reports of de novo erectile dysfunction, rectal wall injury, or fistula. Fifty-seven percent of the Treatment and Crossover subjects did not report any procedure or device related AEs. Eighty percent of the adverse events reported occurred within the first 30 days post-procedure and were typically of short duration.

There was a total of 6 procedure and/or device related Serious Adverse Events (SAE) reported in a total of 4 Treatment and Crossover subjects. One subject experienced extended urinary retention due to untreated intravesical lobe protrusion. A second subject had an allergic reaction to Xanax and was admitted to the hospital for nausea and vomiting. A third subject experienced bladder neck contracture and bladder calculi, which resolved within 30 days. A fourth subject was diagnosed with urosepsis following cystoscopy, which resolved with medication.

As of February 9, 2019, 89% of the adverse events have resolved. The remaining ongoing events listed will be assessed at the patients' next clinical study follow up visits. Events will be updated annually out to five years.

Table 3. All Adjudicated Procedure and/or Device Related AEs for Treatment and Crossover Subjects Through 4 Year Follow-up.

All Adjudicated Procedure and/or Device Related AEs for Treatment and Crossover Subjects Through 4 Year Follow-up Percentage of Subjects					
Adverse Event	**Procedure or Device Related AEs**	**Severity**			**Resolved AEs**
		Mild	**Moderate**	**Severe**	
Dysuria	17%	14%	4%	0%	97%
Hematuria, Gross	12%	11%	1%	0%	100%
Hematospermia	6%	6%	< 1%	0%	100%
Urinary Frequency	6%	5%	1%	0%	82%
Decrease in Ejaculatory Volume	5%	4%	< 1%	0%	33%
UTI, Suspected	5%	4%	1%	0%	100%
Urinary Retention	5%	< 1%	4%	< 1%	100%
Urinary Urgency	5%	3%	2%	0%	78%
Anejaculation	3%	2%	< 1%	0%	0%
Terminal Dribbling	3%	2%	< 1%	0%	60%
UTI, Culture Proven	3%	1%	2%	0%	100%
Epididymitis	2%	< 1%	2%	0%	100%
Erectile Dysfunction, Worsening	2%	2%	< 1%	0%	0%
Gross Hematuria with Clots	2%	1%	< 1%	0%	100%
Hematuria, Intermittent uncomplicated	2%	1%	< 1%	0%	100%
Incomplete Voiding	2%	< 1%	1%	0%	100%
Pain/Discomfort with Ejaculation	2%	0%	2%	0%	100%
Pain/Discomfort, Pelvic	2%	1%	< 1%	< 1%	100%
Pain/Discomfort, Penile	2%	2%	0%	0%	100%
Poor Stream	2%	2%	0%	0%	100%
Prostatitis	2%	1%	1%	0%	100%
Splayed Stream	2%	< 1%	1%	0%	100%
Urethral Stricture	2%	0%	2%	0%	100%
Gross Hematuria with retention	1%	0%	1%	0%	100%
Hematuria, Micro	1%	1%	0%	0%	100%
Urinary Incontinence, Urge	1%	< 1%	< 1%	0%	100%
Urinary Tract Infection (UTI)	1%	1%	0%	0%	100%
Total	**43%**	**36%**	**21%**	**2%**	**89%**

The following events were reported in < 1% of subjects and were mild or moderate in severity unless otherwise indicated: anxiety, bladder neck contracture (severe), bladder stone formation (severe), catheter malfunction, decrease in orgasm pleasure, delay in healing, fever, hesitancy, irritative voiding symptoms, nausea, pain/discomfort (right testicle, abdomen, leg, other, perineum), prostate perforation, phlebitis of arm, prostatic calculi, pyuria, retrograde ejaculation, urosepsis following cystoscopy (severe), shingles on left lower thigh, urethral injury, urinary incontinence (mixed, stress (resolved)), vomiting, hypotension.

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Other Potential Adverse Events

The following adverse events have not been reported in these clinical trials: de novo erectile dysfunction, pelvic abscess, rectal wall injury, and fistula. Delivering a form of thermal therapy or misuse of the device has the potential for producing these adverse effects.

Pain Management

The clinical study did not require specific medications to be used and investigators were instructed to use their clinical judgment in determining what medications, if any, to use on a subject-by-subject basis. Of the 196 subjects treated in the study 135 (69%) received oral sedation, 41 (21%) received a prostate block, and 20 (10%) received IV sedation.

Table 4. Types of Medication Used.

Types of Medication	# of Subjects (N=196)	Percentage of Subjects
Oral Pain Medication	135	69%
Prostate Block	41	21%
IV Sedation	20	10%

Catheterization

Catheterization occurred prior to discharge in 90% of subjects (122 subjects) in the Treatment Arm and 20% of subjects (12 subjects) in the Control Arm. Of the 122 subjects in the Treatment Arm who were catheterized immediately post-procedure, 68% (83 subjects) were catheterized due to "physician discretion." The mean duration of immediate post-procedure catheterization was 3.4 days for subjects in the Treatment Arm and 0.9 days for subjects in the Control Arm. This difference in catheterization rates for the two arms of the Study is to be expected due to the fact subjects in the Treatment Arm received thermal vapor treatments resulting in anticipated inflammatory healing effect.

Table 5. Catheterization.

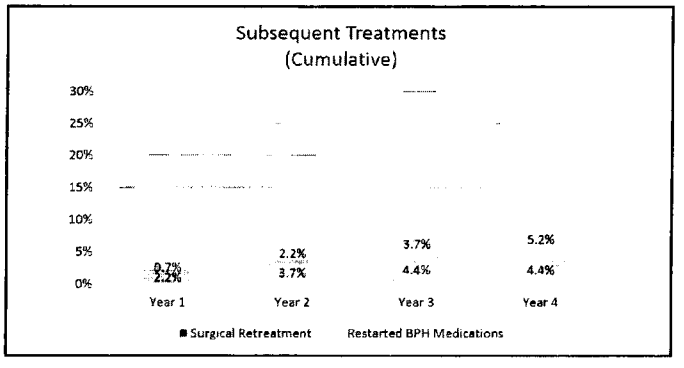
Subjects with catheterization performed	Treatment (N=135)	Control (N=61)
	90.4% (122/135)	19.7% (12/61)
Duration of catheterization, days **Mean ± Std (N)** **Median [Min - Max]**	3.4 ± 3.2 (123) 2.9 (0.0 - 30.9)	0.9 ± 0.8 (12) 0.9 (0.0 - 2.0)

Four subjects with a treated median lobe were re-catheterized due to retention for an average of 5 days. An additional 3 subjects were re-catheterized due to multiple cystoscopic examinations outside of the protocol during the early tissue healing phase (first 90 days post-procedure).

Subsequent Treatments

Out of 188 subjects treated in the Treatment Arm, and Crossover group 9 subjects (5%) sought alternative treatment options within 4 years post initial Rezūm™ treatment.

Graph 4. Subsequent Retreatments (Cumulative).



Supplier's Declaration of Conformity 47 CFR § 2.1077 Compliance Information		
Unique Identifier:	Rezūm	M006D2201-003 GTIN 08714729992547 G2200-003 GTIN 0855357006003
Responsible Party – U.S. Contact Information	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 508-382-9555 www.bostonscientific.com	
FCC Compliance Statement:	This device complies with Part 18 of the FCC Rules	
For further information, see FCC web site for a complete description of all requirements.		

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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InnoView is a registered trademark of InnoView GmbH.

Richard-Wolf is a registered trademark of Richard Wolf GmbH.

Tyvek is a registered trademark of DuPont.

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EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
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USA Customer Service 888-272-1001

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NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

REPLY BRIEF
August 15, 2022 14:17

By: RACHELLE V. ANDERSON 9006814

Confirmation Nbr. 2627497

VESELJKO STOJANOVIC, ET AL

vs.

BOSTON SCIENTIFIC CORPORATION, ET AL

CV 22 963537

Judge: ANDREW J. SANTOLI

Pages Filed: 8

COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC, et al., Plaintiffs, vs. BOSTON SCIENTIFIC CORPORATION, et al., Defendants.	)	Civil Action No. CV-22-963537 **REPLY IN SUPPORT OF DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS**

Rather than dispute Boston Scientific's dispositive matter-of-law arguments, Plaintiffs try to distract the Court with exaggerations and contentions that are irrelevant to the Motion to Dismiss. Not only are many of these contentions demonstrably false, but Plaintiffs' argument does not change well-established Ohio law. Simply put, it is entirely unclear what causes of action Plaintiffs intend to pursue in this litigation—providing Boston Scientific with no notice—and as pleaded, these claims fail as a matter of law.

I. PLAINTIFFS AGREE THEIR RES IPSA LOQUITOR AND UNDEFINED FDA CLAIMS ARE NOT RECOGNIZED CAUSES OF ACTION.

Plaintiffs explicitly pleaded claims for res ipsa loquitur (Count II) and FDA-violations (Count III). And as explained in Boston Scientific's moving brief, these are not recognized causes of action under Ohio law. *See* Br. at 7-9. While Plaintiffs act perplexed as to why Boston Scientific believed these were pleaded causes of action—*notwithstanding the fact that they were pleaded as independent "counts"*—they now agree that neither is a stand-alone cause of action. *See* Plfs.' Opp. at 8-12. Plaintiffs explain these counts were intended to provide background for other causes

of actions (also titled "counts"). To the extent the Court construes Count II and Count III as pleaded causes of action, they must be dismissed.

II. PLAINTIFFS WITHDRAW THEIR NEGLIGENCE PER SE AND EMOTIONAL DISTRESS CLAIMS.

Common law claims for negligence per se (Count IV) and emotional distress (Count XIII) have been abrogated by the OPLA. *See* Br. at 6-7. While Plaintiffs (incorrectly) argue these claims have not been abrogated, Plaintiffs nonetheless state they are not pursuing them in this litigation as causes of action. *See* Plfs.' Opp. at 12 (stating that "[n]egligence per se is not a cause of action" here but rather a "concept for imposing liability" for their other claims); *id.* at 16 (explaining here it is a "damages claim," not a cause of action).

Accordingly, these arguments are now moot, and the Court need not resolve the parties' disagreement on abrogation: Plaintiffs agree they are not pursuing these claims as independent causes of action here. Therefore, to the extent the Court construes Count IV and Count XIII as pleaded causes of action, they must be dismissed.

III. PLAINTIFFS' REMAINING SUBSTANTIVE CLAIMS ARE ABROGATED BY THE OPLA.

After stating they are not pursuing claims for res ipsa loquitor, FDA violations, negligence per se, or emotional distress, Plaintiffs' remaining substantive claims are abrogated by the OPLA. *See* R.C. 2307.71(B) (expressly abrogating "all common law product liability claims or causes of action.").[1]

[1] Plaintiffs generally contend that Boston Scientific relied on federal pleading standards to make this argument. This is false. While Boston Scientific cited to federal cases, each was to illustrate that courts have repeatedly determined these claims are abrogated and fail as a matter of law—none of these cases determined they were inadequately pleaded under *Iqbal* or *Twombly* as Plaintiffs wrongly contend. As illustrated below, federal and state cases are consistent regarding abrogation.

a. Negligence, strict liability, and warranty claims (Counts I, V, VI, VII, VIII, X, and XI)

Plaintiffs do not dispute that common law negligence, strict liability, and warranty claims are abrogated under the OPLA. This is uncontroversial. *See, e.g.*, *Michelson v. Volkswagen Aktiengesellschaft*, 2018-Ohio-1303, 99 N.E.3d 475, ¶ 28 (8th Dist.) (affirming dismissal of negligence claim under Ohio's pleading standard because it was abrogated by the OPLA, and collecting cases that have done the same); *Parker v. ACE Hardware Corp.*, 2018-Ohio-320, ¶ 34, 104 N.E.3d 298, 306 (affirming dismissal of common law product liability claims because they were abrogated by the OPLA, and looking to whether the plaintiff cited to statutes in their pleading in determining if they were common law or statutory claims). Plainly put, the OPLA "extinguishes any common-law claim that, as pled, actually meets the statutory definition of a product liability claim." *Volovetz v. Tremco Barrier Sols., Inc.*, 2016-Ohio-7707, 74 N.E.3d 743, ¶ 33 (10th Dist.). And the definition of an OPLA product claim patently encompasses Plaintiffs' negligence, strict liability, and warranty claims:

> "Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> > (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> >
> > (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> >
> > (c) Any failure of that product to conform to any relevant representation or warranty.

R.C. 2307.71(A)(13).

The court's decision in *Rodgers v. Genesis Healthcare Sys., Inc.* is instructive of this rule as applied to Ohio's pleading standard. 2016-Ohio-721 (5th Dist.). There, the plaintiff alleged a product liability claim (phrased as negligence) against a drug manufacturer. *Id.* at ¶ 4. The manufacturer filed a motion to dismiss on the grounds that "common law product liability claims are abrogated by the Ohio Products Liability Act", and the court dismissed the claim. *Id.* at ¶¶ 6-7. On appeal, the court explained that a review of the complaint showed they were common law claims and abrogated as a matter of law:

> The Ohio General Assembly has codified products liability law in R.C. 2307.71, et seq, thereby abrogating common law product liability claims. Accordingly, a plaintiff must set forth a products liability claim in accordance with statutory requirements. ***A review of appellant's complaint does not show compliance with the Ohio Products Liability Act, let alone reference the statute.*** Accordingly, appellant's complaint fails to state a claim upon which relief can be granted against Purdue Pharma.

Id. at ¶ 42 (emphasis added).

To avoid this clear-cut case of abrogation of Plaintiffs' common-law claims, Plaintiffs brazenly contend their causes of action were actually pleaded under the OPLA. But Plaintiffs saying so does not make it true. Plaintiffs' negligence, strict liability, and warranty claims do not reference or cite to the OPLA in any manner. In fact, Count VIII cites to the restatement of torts rather than the OPLA. There is nothing in Plaintiffs' complaint that would suggest any of their claims are anything but common law product liability claims.[2]

[2] Plaintiffs' Opposition places a large emphasis on attacking Boston Scientific's argument that OPLA causes of action should reference the OPLA in some manner. Plfs.' Opp. at 4-7. Plaintiff states this is purely a creature of federal pleading standards. Not so. Ohio courts have looked to see if there are references to statutes, including the OPLA, to determine if a cause of action is grounded in common law or a statute. *See Rodgers*, 2016-Ohio-721, ¶ 42 (5th Dist.); *Parker*, 2018-Ohio-320, ¶ 34. Indeed, these courts have cited to federal case law in establishing this point, including the very case Boston Scientific cited to in its Motion to Dismiss: *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) (cited to in *Parker* for this exact proposition). As Ohio

Rather than concede this point, Plaintiffs spend pages explaining how Plaintiffs' negligence, strict liability, and warranty claims are similar to specific OPLA provisions. But Plaintiffs cannot cure their obvious pleading deficiencies by citing to the OPLA in their Opposition—they needed to, but did not, do this in their Complaint. *See Rodgers*, 2016-Ohio-721, ¶ 42 (5th Dist.). Simply put, Plaintiff's last-ditch effort to frame their causes of actions as OPLA violations in their *briefing* does not suffice—the *complaint* is at issue. *See Parra v. Jackson*, 2021-Ohio-1188, 171 N.E.3d 452, ¶ 17 (8th Dist.) ("In considering a Civ.R. 12(B)(6) motion to dismiss, ***the court is limited to the four corners of the complaint***." (emphasis added)). And as currently pleaded, Plaintiffs' claims are abrogated common law claims.

b. Ohio Consumer Protection Statute ("OCPSA") claims (Count IX)

Plaintiffs also want to pursue their product liability claims under the OCPSA. This is impermissible as the OPLA is the sole source of statutory relief for product liability claims. *See Blake v. Interneuron Pharmaceuticals*, S.D.Ohio No. C-1-98-672, 1998 WL 35307753, *1 (Dec. 9, 1998) (explaining that non-OPLA statutory claims primarily rooted in product liability claims are also abrogated because holding otherwise "would basically provide [plaintiffs] with a separate statutory theory of recovery in a products liability case that is precluded under Ohio law").

Indeed, courts have repeatedly held OCPSA product lability claims have been abrogated by the OPLA. *See, e.g.*, *McFarland v. Ethicon, Inc.*, S.D. Ohio No. 2:20-CV-02188, 2020 WL 4464401, at *2 (Aug. 4, 2020) (determining that OCPSA claim was abrogated by the OPLA); *Heide v. Ethicon, Inc.*, N.D. Ohio No. 4:20-CV-160, 2020 WL 1322835, at *4 (Mar. 20, 2020) (***same***); *S.S. v. Leatt Corp.*, N.D. Ohio No. 1-12-CV-483, 2013 WL 3777098, at *2 (July 17, 2013) (***same***); *Harris v. Eli Lilly & Co.*, N.D. Ohio No. 4:12CV2481, 2012 WL 6732725, at *3 (Dec. 28, 2012)

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courts have explained, "[l]ike Fed. R. Civ. Pro. 8, Civ. R. 8(A)(1) also requires 'a short and plain statement of the claim showing that the party is entitled to relief'." *Parker*, 2018-Ohio-320, ¶ 34.

(***same***); *Mitchell v. Proctor & Gamble*, S.D. Ohio No. 2:09-CV-426, 2010 WL 728222, at *5 (Mar. 1, 2010) (***same***); *Bouchard v. Am. Home Prod. Corp.*, N.D. Ohio No. 3:98 CV 7541, 2002 WL 32597992, at *11 (May 24, 2002) (***same***); *Schnell v. Am. Home Prod. Corp.*, N.D. Ohio No. 3:00 CV 7228, 2000 WL 35777837, at *2 (July 11, 2000) (***same***).

With it being well established that the OPLA abrogates product liability claims pursued under the OCPSA, Plaintiff contends that even if their OCPSA claims were abrogated (they are), they can still pursue it as an alternative theory of relief. Plfs.' Opp. at 14. This illustrates Plaintiffs' lack of understanding of abrogation under the OPLA—it is not a question of alternative relief or that the pursuit of an OPLA claim precludes recovery under the OCPSA. Rather, it is that the OPLA provides the ***exclusive*** source of relief for product liability claims. The OCPSA cannot, as a matter of law, provide relief for product liability claims regardless of if an OPLA claim is pursued.

IV. PLAINTIFFS' LOSS-OF-CONSORTIUM CLAIM FAILS WITHOUT ANY OTHER SURVIVING CAUSE OF ACTION.

Plaintiffs do not dispute that their loss-of-consortium claim is derivative of their other causes of action—rendering the only dispute the survival of their primary claims. Therefore, should the Court dismiss Plaintiffs' other claims, their loss-of-consortium claim must fail as well.[3]

CONCLUSION

Confronted with a motion, Plaintiffs attempt to amend their Complaint via briefing, walking back numerous "Counts" and contending that they aren't individual causes of action despite being presented as such in the Complaint. Not only is this impermissible, but it illustrates Boston Scientific's point—namely, as pleaded, Plaintiffs' Complaint fails to place Boston Scientific on notice of the *actual* claims alleged against it. Simply put, in its current form, Boston Scientific would have to guess

[3] Plaintiffs contend Boston Scientific stated their loss-of-consortium claim was also abrogated by the OPLA. This is false; no such representation was made.

as to whether each Count within the Complaint amounts to a theory of liability or is simply meant to allege "supporting facts." Accordingly, Plaintiffs have failed to meeting the pleading standard.

For the foregoing reasons, Boston Scientific respectfully requests the Court dismiss all of Plaintiffs' claims against Boston Scientific with prejudice.[4]

Dated: August 15, 2022

By: */s/ Rachelle V. Anderson*

Rachelle V. Anderson (Admitted *Pro Hac Vice*)
NELSON MULLINS RILEY & SCARBOROUGH, LLP
1600 Utica Avenue South, Suite 750
Minneapolis, MN 55416
Tel: (612) 464-4500
Fax: (612) 255-0739
Rachelle.Anderson@nelsonmullins.com

Sarah L. Bunce (OH Bar No. 0080816)
NELSON MULLINS RILEY & SCARBOROUGH, LLP
1111 Superior Avenue, Suite 530
Cleveland, OH 44144
Tel: (216) 304-6171
Fax: (216) 553-4275
Sarah.Bunce@nelsonmullins.com

[4] Plaintiffs contend several times that Boston Scientific is making fact-based arguments. For example, Plaintiffs state that Boston Scientific "essentially blames the surgical procedure for Plaintiffs' injuries." Plfs.' Opp. at 2. This is untrue and perplexing: Boston Scientific made no factual arguments at any point in its Motion to Dismiss.

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing REPLY IN SUPPORT OF DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS was filed and served this 15th day of August, 2022, via this Court's electronic filing system. Parties may access this filing through the Court's system.

By: */s/ Rachelle V. Anderson*
Rachelle V. Anderson

128545058

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC, ET AL
Plaintiff

BOSTON SCIENTIFIC CORPORATION, ET AL
Defendant

Case No: CV-22-963537

Judge: ANDREW J. SANTOLI

JOURNAL ENTRY

TO GRANT A MOTION TO DISMISS FOR FAILING TO STATE A CLAIM UNDER CIV.R. 12(B)(6), IT MUST APPEAR BEYOND DOUBT THAT THE PLAINTIFF CAN PROVE NO SET OF FACTS ENTITLING HIM/HER TO RELIEF. STATE EX REL. BUSH, 42 OHIO ST.3D 77, 80 (1989). IN THIS CASE, PLAINTIFFS' COMPLAINT LISTS SEVERAL "COUNTS" THAT ARE NOT RECOGNIZED CAUSES OF ACTION, INCLUDING RES IPSA LOQUITUR (COUNT II), VIOLATIONS OF THE FOOD DEVICE COSMETIC ACT (COUNT III), AND "STRICT LIABILITY PURSUANT TO THE RESTATEMENT OF TORTS" (COUNT VIII). PLAINTIFFS ACKNOWLEDGE IN THEIR BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS THAT THESE ARE NOT RECOGNIZED CAUSES OF ACTION AND, ALTHOUGH LISTED AS "COUNTS" IN THE COMPLAINT, THEY WERE MEANT TO PUT DEFENDANTS ON NOTICE OF EVIDENTIARY RULES PLAINTIFFS INTENDED TO USE THROUGHOUT THIS CASE OR REGULATIONS IN SUPPORT OF THEIR CLAIMS. IT IS THUS UNCLEAR WHICH "COUNTS" ARE CAUSES OF ACTION PLAINTIFFS INTEND TO PURSUE AND WHICH ARE NOT. THEREFORE, PLAINTIFFS ARE GIVEN 14 DAYS FROM THE DATE OF THIS ENTRY TO FILE AN AMENDED COMPLAINT WHICH CLEARLY STATES THE RECOGNIZED CAUSES OF ACTION THAT THEY ARE PURSUING. DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS, FILED ON 6/24/22, IS HELD IN ABEYANCE UNTIL AFTER PLAINTIFF HAS FILED THEIR AMENDED COMPLAINT.

Judge Signature 08/30/2022

08/30/2022

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NAILAH K. BYRD
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1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

AMENDED COMPLAINT $75
September 6, 2022 15:28

By: WILLIAM A. CARLIN 0009144

Confirmation Nbr. 2644689

VESELJKO STOJANOVIC, ET AL

vs.

BOSTON SCIENTIFIC CORPORATION, ET AL

CV 22 963537

Judge: ANDREW J. SANTOLI

Pages Filed: 20

IN COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

VESELJKO STOJANOVIC
3013 Arrow Lane
Parma, Ohio 44134

And

RANKA STOJANOVIC
3013 Arrow Lane
Parma, Ohio 44134

Plaintiffs

vs.

BOSTON SCIENTIFIC CORPORATION
c/o Its Statutory Agent
Corporation Service Company
84 State Street
Boston, MA 02109

And

CLEVELAND CLINIC FOUNDATION
AKA CLEVELAND CLINIC
c/o Its Statutory Agent
CT Corporation System
1300 East 9th Street
Cleveland, OH 44114

And

MOHAMED ELTEMAMY, M.D.
Cleveland Clinic Foundation
9500 Euclid Ave.
Cleveland, OH 44195

CASE NO: CV-22-963537

JUDGE ANDREW J. SANTOLI

AMENDED COMPLAINT

Affidavit of Merit included herein.
Jury Demand Endorsed herein

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And

JOHN/JANE DOE (1-5)
Any Physician or other Health Care Provider responsible for the Care and treatment of Veseljko Stojanovic (names and addresses unknown)

And

DOE CORPORATION/ PARTNERSHIP 1-5)
Any Corporation or other Business Entity whose Employees and/or Agents were responsible for the care and treatment of Veseljko Stojanovic, (names and addresses unknown)

And

JOHN/JANE ROES (5-10)
Any representative of Boston Scientific Corporation who delivered the Rezum product into Ohio. Any Boston Scientific Corporation representative who was Present when Plaintiff underwent a Cystoscopy utilyszing the Rezum delivery system (names and addresses unknown)

And

JOHN/JANE ROES (10-25)
Individuals or corporations who designed or delivered the Rezum product into Ohio (names and Addresses unknown)

Defendants

Now comes Plaintiffs, Veseljko and Ranka Stojanovic and for their cause of action against the Defendants state the following:

FACTS COMMON TO ALL COUNTS

1. At all times herein, Veseljko Stojanovic ("Mr. Stojanovic") and Ranka Stojanovic ("Mrs. Stojanovic") (collectively "Plaintiffs") were husband and wife and were residents of Cuyahoga County, Ohio.

2. The Defendant, Cleveland Clinic Foundation ("Cleveland Clinic") is and was a healthcare provider who held itself out to the public, including the Plaintiffs, as having the requisite skilled personnel, staff and equipment to render quality Healthcare Services and at all times pertinent herein, were responsible for its employees and apparent employees, including Dr. Mohamed Eltemamy ("Dr. Eltemamy") and others who were present while treatment and care were rendered to Mr. Stojanovic, while within the scope or apparent scope of their employment with Cleveland Clinic.

3. At all times relevant herein, Defendants John/Jane Doe (1-5) and Doe Corporation and/or Partnership (1-5) were physicians or other licensed health care providers responsible for the care and treatment of Plaintiff and who held themselves out to the general public, including Plaintiff, as being capable of providing quality medical care or were Ohio corporations or other business entities licensed to do business in Ohio, which employed and/or contracted with medical, nursing and other health care professionals responsible for the care and treatment of Plaintiff. It is further believed that Defendants John/Jane Doe (1-5) were employees and/or apparent employees of Cleveland Clinic. Despite the exercise of due diligence, the Plaintiff has been unable to ascertain the true identity of these Defendants.

4. At all times herein, Boston Scientific Corporation ("Boston Scientific") was a Corporation or other business entity with its principal place of business in Massachusetts

and was engaged in doing business throughout the state of Ohio, and elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise placed in the stream of commerce a certain medical device, including, but not limited to, a certain product known as Rezum, which is sold as a delivery system kit to treat benign prostatic hyperplasia ("BPH") together with its component parts, (hereinafter referred to as "Rezum"), which product was delivered and sold in the state of Ohio and elsewhere.

5. At all times material to the within cause of action, Defendants John/Jane Doe (5-10), representatives of Boston Scientific who were engaged in doing business throughout the State of Ohio and elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise placed in the stream of commerce the Rezum delivery system, in Ohio and elsewhere, including any representative of Boston Scientific Corporation who was present during the Plaintiff's treatment that utilized the Rezum delivery system. Despite diligent efforts, the identity of John/Jane Doe Representative of Boston Scientific remains unknown.

6. At all times material to the within cause of action, Defendants Doe Corporation 1-5 and Defendants John/Jane Roes (10-25) were individuals and/or corporations or partnerships engaged in doing business throughout the State of Ohio, and elsewhere, specifically having designed, manufactured, assembled, packaged, repaired, refurbished, reconditioned, marketed, sold, advertised, or otherwise took action with respect to certain medical devices, including the Rezum delivery system, which was placed into interstate commerce, in Ohio and elsewhere.

7. On or about June 2, 2021, the Plaintiff underwent a cystoscopy utilizing Rezum, to

treat BPH and as a result of Defendant's failure to provide the Plaintiff with competent, safe and acceptable care and treatment, the Plaintiff was permanently injured.

8. The defendant, Dr. Eltemamy, negligently utilized the Rezum product and/or the Rezum product was defective in accordance with O.R.C. §2307.76, which caused permanent injury to Plaintiff's prostate and/or bladder and/or bladder neck and plaintiff is now unable to control his ability to urinate. Pursuant to R.C. § 2315.18 (B)(3)(a), the Plaintiff has lost the use of a bodily organ system and therefore there is no limitation on the amount of compensatory damages that represent damages for non-economic loss. (The Affidavit of Merit of Dr. David Chaikin is attached as Exhibit "A".)

9. As a direct and proximate cause of the negligence of Dr. Eltemamy in the utilization of the Rezum product and/or a defective Rezum product, in accordance with O.R.C. §2307.76, Mr. Stojanovic was required to undergo further surgical procedures, including the placement of a suprapubic tube to drain urine from his bladder. As a proximate cause of the additional post Rezum surgical procedures, Mr. Stojanovic sustained a permanent physical deformity and pursuant to R.C. §2315.18 (B)(3)(a), there is no limitation on the amount of compensatory damages that represents damages for non-economic loss.

10. At all times relevant herein, the Defendant, Dr. Eltemamy, was and is an individual who was licensed to practice medicine in the state of Ohio and was employed or apparently employed by Cleveland Clinic and/or was operating within the scope of his employment or apparent employment with Cleveland Clinic.

11. At all times herein, Dr. Eltemamy was acting within the scope and course of his employment and/or apparent employment with Cleveland Clinic and held himself out to the public, including the Plaintiff, as having the requisite skills and ability to render quality

Healthcare Services.

12. The Defendants, Dr. Eltemamy, Cleveland Clinic and John/Jane Does, negligently provided services to the Plaintiff and they failed to follow, meet and conform to the standard of care in providing healthcare services under similar circumstances, in Cuyahoga County and other places.

13. The Defendants, Dr. Eltemamy, Cleveland Clinic and John/Jane Does were negligent in failing to hire employees that could and would adopt and practice accepted procedures for providing healthcare to patients and the Defendants failed to enforce said procedures in accordance with accepted practices in providing healthcare in the counties of Northern Ohio and other similar communities in the United States.

14. The Defendants, Dr. Eltemamy, Cleveland Clinic and John/Jane Does failed to hire employees who would follow procedures and they failed to establish appropriate training, standards and procedures for those employees providing services to their patients.

COUNT I
NEGLIGENCE
Dr. Eltemamy, Cleveland Clinic and unknown representatives of Boston Scientific Corp.

15. Plaintiffs hereby incorporate paragraphs 1 through 14 as though fully restated herein.

16. The Plaintiff was a patient of Dr. Dr. Eltemamy and the Cleveland Clinic and had consultations with Dr. Dr. Eltemamy regarding urination which apparently were related to BPH.

17. The Plaintiff had difficulties with urination prior to the procedure on June 2, 2012. However, after the procedure and to this day, the Plaintiff is unable to control his ability to urinate.

18. It is believed and therefore averred that an unknown representative of Boston Scientific was present when Dr. Eltemamy utilized the Rezum delivery system in the course of the procedure that was administered to the Plaintiff at the Cleveland Clinic on or about June 2, 2021 and negligently misguided Dr. Eltemamy in the use of the Rezum product or negligently failed to intervene when it would have been appropriate to do so.

19. As a direct and proximate result of the negligence of Dr. Eltemamy, Cleveland Clinic, and an unknown representative of Boston Scientific Corporation the Plaintiff was denied effective medical, nursing and related Healthcare Services that were administered on/or about June 2, 2021 and thereafter at the Cleveland Clinic which resulted in permanent injury to the Plaintiff.

20. The Defendants set forth in this Count, were in complete control of the procedure that resulted in the injury to Plaintiff and they alone had the means of knowing what occurred consequently, the plaintiff submits that this is the kind of injury that does not normally occur in the absence of negligence. (Res Ipsa Loquitur)

COUNT II
Respondeat Superior

21. Plaintiffs hereby incorporate paragraphs 1 through 20 as if fully restated herein.

22. Plaintiff states that the defendant Cleveland Clinic is responsible for the negligence of any of their employees, staff and or agents, including Dr. Eltemamy, and any person and/or John/Jane Doe who was present when the Plaintiff underwent his treatment for BPH on June 2, 2021, and the Cleveland clinic is therefore responsible for the negligence of their employees, staff and/or agents and/or apparent employee's and apparent staff and/or agents, and other persons through the Doctrine of Respondeat Superior.

COUNT III
Claims against Boston Scientific Pursuant to Chapter 2307

23. Plaintiffs hereby incorporate paragraphs 1 through 22 as if fully restated herein.

24. The Plaintiff is a claimant who experienced economic and non-economic loss as a result of being exposed to a foreseeable risk and suffered harm pursuant to O.R.C. § 2307.71.

25. Boston Scientific is a manufacturer of the Rezum medical device, a product as set forth in O.R.C. §2307.71. Further, Dr. Eltemamy was a Physician as set forth in §2307.71 when he utilized the Rezum device which was unavoidably unsafe pursuant to §2307.71.

26. It is believed and therefore averred that prior to on/or about June 2, 2022, representatives of Boston Scientific, the names and identities remain unknown despite diligent efforts to determine who they were, produced advertisements, made affirmations and Rezum instructions, promises and descriptions that the Rezum delivery system was safe and fit for its intended use.

27. It is believed and therefore averred, that Boston Scientific failed to instruct, train or require certifications of physicians utilizing the Rezum delivery system, to ensure that those physicians controlling and operating the Rezum delivery system were properly trained on using the product, including, but not limited to, a working understanding of the application of treatments with Rezum and potential consequences of misuse of the Rezum medical device.

28. It is believed and therefore averred, that Boston Scientific failed to properly train and instruct Dr. Eltemamy in the proper and safe use of the Rezum delivery system, or to insure that users of the product were properly trained prior to utilizing said medical device.

29. At all times relevant herein, the United States Food and Drug Administration

("F.D.A.") was and is the federal agency of the United States responsible for approving medical devices pursuant to the medical device Amendments of 1976 to the Food Device Cosmetic Act ("FDCA").

30. In effect, the F.D.A. enforces the FDCA and ensures among other things, that medical devices intended for use in human beings are safe and effective for its intended use, and that the physicians responsible for utilizing the device, are properly trained and that the labeling of such medical devices are true and accurate information. The F.D.A. requires that all medical devices must be demonstrated to be safe and effective for each intended use. A manufacturer is required to give adequate directions for the use of a medical device such that a "Layman can use a device safely and for the purpose for which it is intended", 21 C. F. R. § 810.5 (2012) and to conform to Section 801.15 requirements governing the appearance of the label.

31. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling and false and misleading labeling is considered misbranded, which is prohibited. (21 U.S.C. § 321, 352 and 331).

32. The distribution of a misbranded medical device is prohibited pursuant to 21 U.S.C. § 331 (a), (k)(2012) and 21 U.S.C. § 352 (F) (2012).)

33. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written when the manufacturer has failed to disclose those adverse events to the F.D.A. or failed to determine the causes of the adverse events. Therefore, the labeling becomes inadequate, and the product is misbranded which results in a violation of the Ohio Product Liability Claims Act pursuant

to Chapter 2307 of the O.R.C.

34. Pursuant to the FDCA and F.D.A.'s implementing regulations, labeling, promotional advertisements and making claims about medical devices are deemed misleading if they fail to disclose certain information about the products risks, particularly those risks that have been gleaned from adverse events reported by physicians and consumers use of the Rezum product. Consequently, in order to comply with the F.D.A.'s implementing regulations, such promotional pieces must reveal material facts about the product being promoted, including facts about the consequences that can result from use or misuse of the product, as suggested in the promotional piece or from reported adverse events. A medical device, including the Rezum product, distributed by Boston Scientific, is deemed to be misbranded and in violation of O.R.C. Chapter 2307, if its labeling is false or misleading in any particular regard. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about adverse events that can result from use of the product.

35. Boston Scientific is further required to report to the F.D.A., "no later than 30 calendar days after the day: the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer may have caused or contributed to death or serious injury or malfunctioned. (21 C.F.R. Section 803.50 (a) (2012).

36. Reports to the F.D.A. are to contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event and

must evaluate the cause of the adverse event. (21 C.F.R. § 803.50 (a) (2012).

37. Manufacturers, like Boston Scientific, are required to make periodic reports to the F.D.A. regarding approved devices, such reports must include summaries of unpublished reports of data from any clinical investigation or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to Boston Scientific. It is also required that any negative or harmful reports in the scientific literature concerning the device and known to or that reasonably should be known to Boston Scientific be divulged to users of the device. (21 C. F. R. § 814.84 (b)(2)(2012)). Further, Boston Scientific had a continuing duty to monitor the Rezum product after premarket approval and to discover and report to the F.D.A. any complaints about the product's performance and any adverse events of which it became aware and that are or may be attributable to the Rezum delivery system or potential misuse of the system by physicians. The failure to provide post marketing warnings by Boston Scientific was a violation of O.R.C. §2307.76.

38. Boston Scientific is further required to establish internal procedures for reviewing complaints and adverse event reports. Consequently, Boston Scientific is required to "establish and maintain" an adverse event database in which they describe in every individual any adverse event report, whether remedial action was taken with regard to the adverse event and whether the remedial action was reported to the F.D.A as a removal or correction of the device. (21 C.F.R. § 803.50 (2012)).

39. Boston Scientific is further required to disclose any reportable medical device reporting event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, within 5 days after

becoming aware of such event or events.

40. It is believed, and therefore averred, that Boston Scientific violated the aforementioned statutes and regulations by falsely and misleadingly promoting the Rezum delivery system, by failing to report to the F.D.A. adverse events, by failing to timely conduct failure investigations and analysis, by failing to timely report any and all information concerning product failures and corrections, by failing to inform the F.D.A. of unanticipated adverse events, by failing to report increases in the incidence of adverse events and device failures necessitating a labeling, manufacturing or device notification or warning, failed to conduct necessary design validation's, selling and distributing a misbranded product by failing to disclose the potential risks of the Rezum delivery system, including the consequences of overtreating. These failures constitute negligence per se and per se violations of the Ohio Product Liability Act.

41. The Manufacturer and User Facility Device Experience ("MAUDE") represents reports of adverse events involving medical devices, including the Rezum delivery system manufactured by Boston Scientific. It is believed and therefore averred that the utilization of Rezum resulted in over 300 adverse events by patients treated with the Rezum delivery system and failed to warn the Plaintiff's healthcare providers and/or the Plaintiff of those risks of the procedure, wherein the Rezum, excel delivery system is utilized. (The MAUDE adverse events for Rezum are in excel format so it cannot be attached but will be made available to the Court and any Defendant and are incorporated herein by reference.)

42. As a direct and proximate result of the actions and/or inactions of the Defendant Boston Scientific, the Plaintiff sustained permanent injury which is requiring the Plaintiff to undergo additional procedures and surgeries to correct the injuries that he sustained as a

result of the Rezum procedure.

43. Defendant Boston Scientific had an obligation to follow those laws and regulations set forth by the F.D.A., regarding the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, product preparation for use, and warning of the risks and dangers of the Rezum delivery system.

44. As a direct and proximate result of the actions and/or inactions of Defendant, Boston Scientific Corporation and/or its unknown affiliates and/or agents set forth in the Fictitious Names paragraphs of this Complaint, placed in the stream commerce, a defective product pursuant to O.R.C. §2307.74 through § 2307.77, which caused Plaintiff to sustain serious and permanent personal injuries requiring the care and treatment of physicians and medication and has been and will in the future, continue to be hampered in his daily routines and suffered harm as set forth in O.R.C. §2307.71(A)(7).

45. The Defendant's representations and promises regarding the Rezum delivery system, had the natural tendency to those who are in need of BPH treatment, including Plaintiff herein, to utilize Rezum in reliance upon those false representations which caused the product to be defective in accordance with O.R.C. §2307.77.

46. The Rezum delivery system, did not conform to Boston Scientific's representations that the device was safe and would not produce serious side effects. The Rezum delivery system, did not conform to Boston Scientific's promises, descriptions and were not adequately packaged, labeled, promoted, or fit for the ordinary purpose for which it was intended. The defendants misrepresented that physicians and surgeons utilizing the Rezum delivery system would be properly trained in all aspects of its use, and properly certified in using Rezum in violation of the Ohio Product Liability Act.

47. Through Boston Scientific's public statements, descriptions of the device promises relating to the Rezum delivery system and in the Rezum delivery device kit for BPH Defendant's expressly represented that the device was efficacious and safe for its intended use. Plaintiffs further allege that all written materials that the Defendant utilized, including on the websites, led the plaintiff to reasonably believe that the Rezum delivery system, would be safe, and if there were adverse events of potential risks of using the device, that Boston Scientific would provide warnings regarding those adverse events and risks.

48. The Defendant, Boston Scientific, placed the Rezum product into the stream of commerce and intended that the Rezum delivery system be used in the manner that the Plaintiff and his physician herein used it. When the Rezum system was used in the intended manner, the Defendants represented each device to be safe and fit for such use; and represented those physicians utilizing Rezum were properly trained and warned of potential injuries and malfunctions that users of the Rezum delivery system sustained as set forth in MAUDE, which deomonstrated the Rezum product to be defective in accordance with O.R.C. §2307.75. Boston Scientific failed to disclose the foreseeable risks of the Rezum device which exceeded its benefits. The risks posed by the Rezum device were not recognized by the Plaintiff or any prudent consumer.

COUNT IV
Violation of ORC 2307.76

49. Plaintiff hereby incorporates paragraphs 1 through 48 as if fully restated herein.

50. The Defendant was fully aware of the adverse events of the Rezum product through MAUDE and failed to inform the plaintiff and his physicians about the risks involved therein.

51. Boston Scientific failed to provide warnings to physicians and consumers,

including plaintiff, who was unaware of the hundreds of adverse events that the Rezum delivery system had generated and their failure to warn the plaintiff and physicians of those risks and post marketing risks caused harm to the plaintiff for which the plaintiff seeks to recover compensatory damages.

52. Boston Scientific failed to provide those warnings when it was aware of the adverse events and was aware that Rezum delivery system would cause and was aware of the type of harm which the Rezum delivery system was causing to Plaintiff's and other patients.

53. As a direct result of the inadequate warnings and instructions to the Plaintiff, he suffered permanent injuries.

COUNT V
Violation of O.R.C. 2307.76 and 2307.77

54. Plaintiff hereby incorporates paragraphs 1 through 53 as if fully restated herein.

55. Boston Scientific specifically set forth in their Rezum delivery device kit for BPH prescriptive information, that they required physicians training specific to the Rezum system procedure prior to physicians using the Rezum device. It is believed and therefore averred, that Boston Scientific did not require certifications of training and did not require and/or did not insure those physicians utilizing the Rezum device, including Dr. Eltemamy, were adequately trained on the device and were aware of any injuries that could be caused through misuse of the device.

56. As a direct result of the falsity of Boston Scientific's representations, O.R.C. §2307.76 and O.R.C. §2307.77 were violated and was a proximate cause of injury to the Plaintiff.

COUNT VI
***Violation of the Magnuson*-Moss act – 15 U.S.C. § 2301, et seq.**

57. Plaintiffs hereby incorporate paragraphs 1 through 56 as if fully restated herein.

58. Defendants impliedly warranted that the Rezum product was fit for the ordinary purposes for which it was supposed to be used.

59. Defendants also impliedly warranted that the Rezum device was adequately packaged and labeled.

60. Defendant breached the aforementioned implied warranties of merchantability inasmuch that the Rezum delivery system was unsafe, when used as directed and for its ordinary purposes.

61. Defendants, Boston Scientific also breached the aforementioned implied warranties of merchantability inasmuch as the Rezum delivery system lacked adequate warnings and instructions for its safe and ordinary use and they failed to provide adequate warnings and instructions for their physicians as they represented in their delivery device kit for BPH.

62. As a direct and proximate result of Defendants' breaches of warranty, plaintiff has suffered personal injuries, medical expense, pain, suffering, permanent disability, permanent scarring and disfigurement, emotional distress, and other economic and non-economic loss

63. As a direct and proximate result of Defendants' breaches, plaintiff's damages are in an amount to be determined at trial, which amount exceeds $25,000.00

COUNT VII
Violations of Ohio Consumer Protection Statute

64. Plaintiffs hereby incorporate paragraphs 1 through 63 as if fully restated herein.

65. The Plaintiff alleges that he is a consumer entitled to the protections of the Consumer Sales Practices Act, O.R.C. § 1345.01 et seq. and that he received treatment from the Rezum delivery system as manufactured, marketed and supplied by the Defendant.

66. The Defendant Boston Scientific, supplied Plaintiff's medical provider with the Rezum delivery system, and accordingly is a supplier in connection with the consumer transactions pursuant to O.R.C. § 1345.01 et seq.

67. The Defendant, Boston Scientific, deceived the Plaintiff in violation of O.R.C. §1345.02 (a) of the act by promoting, soliciting, effecting and/or allowing sales with the use of unfair, false, misleading or deceptive acts or practices to Plaintiff, either directly or indirectly through his medical provider.

68. The Defendant engaged in deceptive acts or practices in violation of O.R.C.§ 1345.02 (B)(2) as a supplier in connection with consumer transactions in that the Defendant knew at the time that the transactions were entered into that they deceptively withheld and actively represented that the Rezum delivery system was of a particular standard, quality grade or prescription and the physicians use of Rezum would require certified training.

69. Defendant engaged in unconscionable acts and practices pursuant to O.R.C. §1345.03(B)(6).

70. The Defendant knowingly accepted the benefits of its deception in the form of profits and increased sales.

71. The Defendant should have taken affirmative steps to warn consumers, including the Plaintiff, of the potential harm in utilizing the Rezum delivery system and those risks set forth in MAUDE, particularly those risks associated with excess treatment.

72. As a direct and proximate cause of Defendants' deceptive and unconscionable acts and practices, Plaintiff has suffered irreparable personal injury.

73. Plaintiff further alleges that Defendant knowingly committed the acts and practices in violation of the Ohio Consumer Sales Practices and is accordingly responsible for attorney's fees and punitive damages.

COUNT VIII
Loss of Consortium

74. Plaintiffs hereby incorporate paragraphs 1 through 73 as if fully restated herein.

75. Mrs. Stojanovic, Plaintiff's wife, has suffered damages, which include the loss of companionship, care, assistance, attention, protection, advice, counsel, guidance and education. Mrs. Stojanovic also suffered severe mental anguish and emotional distress as a result of the injuries her husband has suffered.

COUNT IX
Emotional Distriss
O.R.C. §2307.71(A)(13)

76. Plaintiffs hereby incorporate paragraphs 1 through 75 as if fully restated herein.

77. The Defendants, as a direct and proximate cause of the negligence herein set forth, have inflicted and caused severe emotional distress to the Plaintiffs. Following the procedure, Mr. Stojanovic suffered frequent, multiple and chronic urinary tract infections, including sepsis, that has posed a direct risk to his transplanted kidney. The Plaintiffs have particularly and emotionally been plagued by the potential loss of kidney function because the chronic infections pose a direct threat to his kidney and kidney function. Every time Mr. Stojanovic stops taking anti-biotics, a urinary tract infection quickly develops, thus reducing his quality of life because he is persistently sick and having to admit himself to hospitals and emergency departments for more antibiotics, which are becoming

increasingly resistant to the bacteria as a direct result of being repeatedly exposed to those antibiotics that are required to address the infections. Mr. Stojanovic never had a urinary tract infection prior to the cystoscopy with utilization of the Rezum delivery system.

WHEREFORE, Plaintiffs demand judgment against all Defendants, jointly and severally, for compensatory and punitive damages for Mr. Stojanovic injuries and the Plaintiffs emotional distress claims, in an amount in excess of Twenty-five Thousand Dollars ($25,000.00), plus interest, attorney fees, the costs of this action and for all other relief that this Court deems just and equitable.

Respectfully Submitted,

/s/ William A. Carlin
WILLIAM A. CARLIN 0009144
29325 Chagrin Blvd., Ste. 305
Pepper Pike, Ohio 44122
TEL: 216/831-4935; FAX: 216/831-9526
WcarlinEsq@aol.com

JURY DEMAND

The Plaintiffs hereby demand a trial by jury on all issues herein.

/s/ William A. Carlin
William A. Carlin 0009144

CERTIFICATE OF SERVICE

I hereby certify that, on September 6th , 2022, a copy of said Amended Complaint was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's system.

/s/ William A. Carlin
William A. Carlin (0009144)

AFFIDAVIT OF DR. DAVID CHAIKIN

STATE OF NEW JERSEY)
) s.s
COUNTY OF MORRIS)

Now comes Dr. David Chaikin and after first being duly sworn, deposes and states the following:

1. That he is licensed to practice medicine in the state of New Jersey;

2. That he reviewed all medical records that reasonably were made available to him as it pertains to the treatment and medical care of Veseljko Stojanovic was a patient at Cleveland Clinic, Cleveland, Ohio;

3. That the Affiant is familiar with the applicable standard of care that would pertain to the medical care that Veseljko Stojanovic received;

4. That Affiant is of the opinion that the standard of care was breached by Dr. Mohamed Eltemany at Cleveland Clinic and was a proximate cause of injuries sustained by Veseljko Stojanovic, while he was in his care at Cleveland Clinic.

AFFIANT SAYS NOTHING FURTHER.

Dr. David Chaikin

The foregoing was subscribed and sworn to before me by **Dr. David Chaikin**, this 11 day of May, 2022,

Brea Grosch
Notary

BREA GROSCH
Notary Public - State of New Jersey
My Commission Expires Aug 6, 2025

EXHIBIT A